



# **KENTUCKY PHARMACY LAWS**



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**UNOFFICIAL TEXT OF STATUTES AND ADMINISTRATIVE REGULATIONS  
FOR INFORMATION ONLY  
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## Kentucky Controlled Substance Act Manual

Copies may be obtained from:

**Cabinet for Health and Family Services  
Office of Inspector General  
Drug Enforcement and Professional Practices Branch  
275 East Main Street, 5ED  
Frankfort, KY 40621  
Phone [502] 564-2815  
[www.chfs.ky.gov](http://www.chfs.ky.gov)**

## Code of Federal Regulations

Copies may be obtained from:

**Federal Controlled Substance Regulations  
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## KENTUCKY REVISED STATUTES - CHAPTER 315

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### **315.002 Declarations of public policy -- Construction of chapter.**

The practice of pharmacy within the Commonwealth is declared to be a professional practice affecting the public health, safety, and welfare, and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, should merit and receive the confidence of the public, and only qualified persons shall be permitted to engage in the practice of pharmacy and ensure the quality of drugs and related devices distributed within the Commonwealth. This chapter shall be liberally construed to carry out these objectives and purposes. The persons entrusted through this chapter to engage in the practice of pharmacy shall be pharmacists. They shall be recognized by the Commonwealth as health care professionals, and, within their statutory scope of practice, providers of pharmacy-related primary care.

**Effective:** July 15, 1996

**History:** Created 1996 Ky. Acts ch. 257, sec. 1, effective July 15, 1996.

### **315.005 Purpose of chapter.**

The purpose of this chapter is to promote, preserve, and protect public health, safety, and welfare by and through effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, control, and regulation of all sites or persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth.

**Effective:** July 15, 2008

**History:** Amended 2008 Ky. Acts ch. 148, sec. 6, effective July 15, 2008. -- Created 1996 Ky. Acts ch. 257, sec. 2, effective July 15, 1996.

### **315.010 Definitions for chapter.**

As used in this chapter, unless the context requires otherwise:

- (1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, or ingestion, whether topically or by any other means;
- (2) "Association" means the Kentucky Pharmacists Association;
- (3) "Board" means the Kentucky Board of Pharmacy;
- (4) "Collaborative care agreement" means a written agreement between a pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:
  - (a) Patients' drug-related health care needs fall within the practitioner's or practitioners' statutory scope of practice;
  - (b) Patients are referred by the practitioner or practitioners to the pharmacist or pharmacists; and
  - (c) The agreement:
    1. Identifies the practitioner or practitioners and the pharmacist or pharmacists who are parties to the agreement;
    2. Specifies the drug-related regimen to be provided, and how drug therapy is to be monitored; and
    3. Stipulates the conditions for initiating, continuing, or discontinuing drug therapy and conditions which warrant modifications to dose, dosage regimen,

dosage form, or route of administration;

(5) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture or manual combination of drug ingredients. "Compounding," as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists;

(6) "Confidential information" means information which is accessed or maintained by a pharmacist in a patient's record, or communicated to a patient as part of patient counseling, whether it is preserved on paper, microfilm, magnetic media, electronic media, or any other form;

(7) "Continuing education unit" means ten (10) contact hours of board approved continuing pharmacy education. A "contact hour" means fifty (50) continuous minutes without a break period;

(8) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription drug in a suitable container, appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;

(9) "Drug" means any of the following:

- (a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;
- (b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;
- (c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
- (d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

(10) "Drug regimen review" means retrospective, concurrent, and prospective review by a pharmacist of a patient's drug-related history, including but not limited to the following areas:

- (a) Evaluation of prescription drug orders and patient records for:
  - 1. Known allergies;
  - 2. Rational therapy contraindications;
  - 3. Appropriate dose and route of administration;
  - 4. Appropriate directions for use; or
  - 5. Duplicative therapies.
- (b) Evaluation of prescription drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions;
- (c) Evaluation of prescription drug orders and patient records for adverse drug reactions; or
- (d) Evaluation of prescription drug orders and patient records for proper utilization and optimal therapeutic outcomes;

- (11) "Immediate supervision" means under the physical and visual supervision of a pharmacist;
- (12) "Manufacturer" means any person, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, compounding, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container;
- (13) "Medical order" means a lawful order of a specifically identified practitioner for a specifically identified patient for the patient's health care needs. "Medical order" may or may not include a prescription drug order;
- (14) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government;
- (15) "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy;
- (16) "Pharmacist intern" means a natural person who is:
- (a) Currently certified by the board to engage in the practice of pharmacy under the direction of a licensed pharmacist and who satisfactorily progresses toward meeting the requirements for licensure as a pharmacist;
  - (b) A graduate of an approved college or school of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;
  - (c) A qualified applicant awaiting examination for licensure as a pharmacist or the results of an examination for licensure as a pharmacist; or
  - (d) An individual participating in a residency or fellowship program approved by the board for internship credit;
- (17) "Pharmacy" means every place where:
- (a) Drugs are dispensed under the direction of a pharmacist;
  - (b) Prescription drug orders are compounded under the direction of a pharmacist; or
  - (c) A registered pharmacist maintains patient records and other information for the purpose of engaging in the practice of pharmacy, whether or not prescription drug orders are being dispensed;
- (18) "Pharmacy technician" means a natural person who works under the immediate supervision, or general supervision if otherwise provided for by statute or administrative regulation, of a pharmacist for the purpose of assisting a pharmacist with the practice of pharmacy;



(19) "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; the administration of influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to individuals fourteen (14) to seventeen (17) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;

(20) "Practitioner" has the same meaning given in KRS 217.015(35);

(21) "Prescription drug" means a drug which:

(a) Under federal law is required to be labeled with either of the following statements:

1. "Caution: Federal law prohibits dispensing without prescription";
2. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian";
3. "Rx Only"; or
4. "Rx"; or

(b) Is required by any applicable federal or state law or administrative regulation to be dispensed only pursuant to a prescription drug order or is restricted to use by practitioners;

(22) "Prescription drug order" means an original or new order from a practitioner for drugs, drug-related devices or treatment for a human or animal, including orders issued through collaborative care agreements. Lawful prescriptions result from a valid practitioner-patient relationship, are intended to address a legitimate medical need, and fall within the prescribing practitioner's scope of professional practice;

(23) "Pharmacy-related primary care" means the pharmacists' activities in patient education, health promotion, assistance in the selection and use of over-the-counter drugs and appliances for the treatment of common diseases and injuries as well as those other activities falling within their statutory scope of practice;

(24) "Society" means the Kentucky Society of Health-Systems Pharmacists;

(25) "Supervision" means the presence of a pharmacist on the premises to which a pharmacy permit is issued, who is responsible, in whole or in part, for the professional activities occurring in the pharmacy; and

(26) "Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 118, sec. 1, effective June 24, 2015. -- Amended 2011 Ky. Acts ch. 81, sec. 1, effective June 8, 2011. -- Amended 2010 Ky. Acts ch. 22, sec. 5, effective July 15, 2010; and ch. 37, sec. 1, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 124, sec. 8, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 18, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 10, sec. 1, effective July 13, 2004. -- Amended 1998 Ky. Acts ch. 297, sec. 4, effective July 15, 1998; ch. 301, sec. 27, effective July 15, 1998; and ch. 531, sec. 3, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 3, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 1, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 1. -- Created 1960 Ky. Acts ch. 234, sec. 1.

**Legislative Research Commission Note** (7/13/2004). 2004 Ky. Acts ch. 10, sec. 2, states that 2004 Ky. Acts ch. 10, sec. 1, which amends this section, shall be known as the Robert L. Barnett, Jr. R. Ph. Act.

**Legislative Research Commission Note** (7/15/98). This section was amended by 1998 Ky. Acts chs. 297, 301, and 531 which do not appear to be in conflict and have been codified together. It is clear that the intent of both 1998 Ky. Acts ch. 297, sec. 4, and ch. 301, sec. 27, was to change the subsection reference in KRS 217.015 for the definition of practitioner. In codifying these Acts, that result has been effectuated. KRS 7.136(1)(e).

**315.020 Only pharmacists to supervise manufacturing of pharmaceuticals or practice pharmacy -- Exceptions -- Persons employed to assist practice of pharmacy after April 1, 2009, to be registered pharmacy technicians or exempt under KRS 315.135.**

(1) No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his place of business except in the presence and under the immediate supervision of a pharmacist.

(2) No manufacturer of pharmaceuticals who is not a pharmacist shall fail to place a pharmacist in charge of his place of business or shall permit any person to compound prescription drugs, medicines, or pharmaceuticals in his place of business, except as provided by the board through the promulgation of administrative regulations pursuant to KRS Chapter 13A.

(3) Except as provided in subsection (4) of this section, no person shall engage in the practice of pharmacy unless licensed to practice under the provisions of KRS Chapter 315.

(4) The provisions of subsection (3) of this section shall not apply to:

- (a) Pharmacist interns performing professional practice activities under the immediate supervision of a licensed pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
- (b) Pharmacist interns and pharmacy technicians performing specifically identified pharmacy practice activities while under the supervision of a pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
- (c) Other licensed health care professionals practicing within the statutory scope of their professional practices; or
- (d) Volunteer health practitioners providing services under KRS 39A.350 to 39A.366.

(5) Effective April 1, 2009, an owner of a pharmacy shall not employ a person to assist in the practice of pharmacy unless the person is registered as a pharmacy technician by the board or exempt under KRS 315.135.

**Effective:** July 15, 2008

**History:** Amended 2008 Ky. Acts ch. 148, sec. 7, effective July 15, 2008. -- Amended 2007 Ky. Acts ch. 96, sec. 15, effective June 26, 2007. -- Amended 1996 Ky. Acts ch. 257, sec. 4, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 2, effective July 15,

1982. -- Amended 1970 Ky. Acts ch. 221, sec. 2. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 2619, 2620, 2628, 2631.

**315.030 Permit required -- License required to represent oneself as pharmacist --  
Registration required to represent oneself as pharmacy technician.**

(1) No person shall take, use or exhibit the title of drug, drug store, pharmacy or apothecary, or any combination of such names or titles, or any title, name or description of like import, or any form designed to take the place of such a title, or use any place with respect to which any of those terms are used in any advertisement or telephone directory listing, unless the facility has been issued a permit by the board.

(2) No person shall call himself or hold himself out as or use the title of "pharmacist," "registered pharmacist," "licensed pharmacist," "druggist," or use the initials "R.Ph." or terms which would imply that he is a pharmacist, unless he is duly licensed under the provisions of KRS Chapter 315.

(3) Effective April 1, 2009, a person shall not call himself or herself or hold himself or herself out as a or use the title of "pharmacy technician" unless the person is duly registered under KRS 315.136 or 315.138.

**Effective:** July 15, 2008

**History:** Amended 2008 Ky. Acts ch. 148, sec. 9, effective July 15, 2008. -- Amended 1982 Ky. Acts ch. 191, sec. 3, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 3. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 1376t.

**315.035 Permit required for operation of a pharmacy -- Application -- Fee -- Issuance -- Fee for failure to renew -- Premises covered by permit -- Rules and regulations -- Requirements for in-state pharmacy doing business through the Internet -- Board may waive permit requirements for out-of-state pharmacy -- Temporary operation of pharmacy during state of emergency.**

(1) No person shall operate a pharmacy within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without having first obtained a permit as provided for in KRS Chapter 315. An application for a permit to operate a pharmacy shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with such reasonable standards and rules and regulations as may be prescribed by the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation promulgated by the board pursuant to KRS Chapter 13A, not to exceed two hundred fifty dollars (\$250).

(2) Upon receipt of an application of a permit to operate a pharmacy, accompanied by the permit fee not to exceed two hundred fifty dollars (\$250), the board shall issue a permit if the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall refuse to renew any permit to operate unless the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof; provided, however, that the board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. In such event, the temporary permit shall be valid for a period of thirty (30)

days, unless extended.

(3) A separate permit to operate shall be required for each pharmacy.

(4) Each permit to operate a pharmacy, unless sooner suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by such reasonable renewal fee as may be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) nor to increase more than twenty-five dollars (\$25) per year. An additional fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.

(5) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable; provided however, that a buyer may operate the pharmacy under the permit of the seller pending a decision by the board of an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(6) The board may promulgate rules and regulations to assure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular pharmacy and to assure reasonable health and sanitation standards for areas within pharmacies which are not subject to health and sanitation standards promulgated by the Kentucky Cabinet for Health and Family Services or a local health department.

(7) Each pharmacy shall comply with KRS 218A.202.

(8) Any pharmacy within the Commonwealth that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall, prior to obtaining a permit, receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar program approved by the Kentucky Board of Pharmacy, accreditation shall be maintained and remain current.

(9) Any pharmacy within the Commonwealth doing business by use of the Internet shall certify the percentage of its annual business conducted via the Internet and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

(10) A pharmacist may temporarily operate a pharmacy in an area not designated on the permit as authorized in KRS 315.500.

**Effective:** July 15, 2010

**History:** Amended 2010 Ky. Acts ch. 22, sec. 6, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 124, sec. 9, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 19, effective June 20, 2005; ch. 61, sec. 1, effective June 20, 2005; and ch. 99, sec. 597, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 548, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 5, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 4, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 1. -- Created 1966 Ky. Acts ch. 260, sec. 6.

**315.0351 Out-of-state pharmacy -- Permit -- Requests for information -- Records -- Toll-free telephone service -- Pharmacist on duty -- Requirements for out-of-state pharmacy doing business through the Internet.**

(1) Every person or pharmacy located outside this Commonwealth which does business, physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth within the meaning of KRS Chapter 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy permit." The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035.

(2) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist.

(3) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the jurisdiction in which it is located.

(4) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed.

(5) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy.

(6) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth.

(7) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to engage in the practice of pharmacy by the Commonwealth that shall be responsible for compliance

by the pharmacy with the provisions of this section.

(8) Each out-of-state pharmacy shall comply with KRS 218A.202.

(9) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current.

(10) Any out-of-state pharmacy doing business in the Commonwealth of Kentucky shall certify the percentage of its annual business conducted via the Internet and electronic mail and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

(11) Any pharmacy doing business within the Commonwealth of Kentucky shall use the address on file with the Kentucky Board of Pharmacy as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner.

(12) The Kentucky Board of Pharmacy may waive the permit requirements of this chapter for an out-of-state pharmacy that only does business within the Commonwealth of Kentucky in limited transactions.

**Effective:** June 26, 2007

**History:** Amended 2007 Ky. Acts ch. 124, sec. 10, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 20, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 107, sec. 4, effective July 13, 2004. -- Created 1990 Ky. Acts ch. 155, sec. 1, effective July 13, 1990.

**315.036 Permit to be acquired by manufacturer -- Fee -- Records required -- Report -- Exception.**

(1) Except as provided in subsection (4) of this section, each manufacturer of drugs shall be required to register with and obtain a permit from the board. Such permit shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.

(2) Manufacturers shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that manufacturers periodically report to the board all drugs manufactured, received, and sold.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice, compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order.

**Effective:** July 15, 2008

**History:** Amended 2008 Ky. Acts ch. 124, sec. 2, effective July 15, 2008. -- Amended 1996 Ky. Acts ch. 257, sec. 6, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 5, effective July 15, 1982.

### **315.040 Exceptions to chapter.**

(1) Nothing in this chapter shall be construed to prevent, restrict, or otherwise interfere with the sale of nonprescription drugs in their original packages by any retailer. No rule or regulation shall be adopted by the Board of Pharmacy under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist.

(2) Nothing in this chapter shall interfere with the professional activities of any licensed practicing physician, or prevent the physician from keeping any drug or medicine that he or she may need in his or her practice, from compounding the physician's own medications, or from dispensing or supplying to patients any article that seems proper to the physician.

(3) Nothing in this chapter shall be construed to interfere with the activities of a midlevel health care practitioner as provided in KRS 216.925.

(4) Nothing in this chapter pertaining to the use of collaborative care agreements shall apply in any hospital or other health facility operated by a hospital without the express written permission of the hospital's governing body. Collaborative care agreements may be restricted by the policies and procedures of the facility.

(5) Nothing in this chapter shall interfere with the activities of a physician assistant as authorized in KRS Chapter 311.

(6) Nothing in this chapter shall interfere with the activities of an advanced practice registered nurse as authorized in KRS Chapter 314.

**Effective:** July 15, 2010

**History:** Amended 2010 Ky. Acts ch. 85, sec. 67, effective July 15, 2010. -- Amended 2000 Ky. Acts ch. 391, sec. 22, effective July 14, 2000. -- Amended 1998 Ky. Acts ch. 228, sec. 6, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 7, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 482, sec. 12, effective July 13, 1990. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 1376t, 2625, 2632.

### **315.050 Qualifications of applicant for licensure -- Examination -- Standards for internship -- Certificate of internship.**

(1) Every applicant for licensure as a pharmacist shall be not less than eighteen (18) years of age, of good mental health and moral character, a graduate of a school or college of pharmacy program approved by the board, and shall file proof satisfactory to the board, substantiated by proper affidavits, of completion of an approved internship.

(2) After the applicant has passed a satisfactory examination conducted before the board under regulations prescribed by the board, he shall be entitled to a license as a pharmacist.

(3) The examination for licensure shall be given by the board at least two (2) times during each year. The examination shall be prepared to measure the competency of the applicant to engage in the practice of pharmacy. The board may employ and cooperate with any

organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed such an examination.

(4) The board shall by regulation establish standards for pharmacist intern certification and an approved internship program and shall determine appropriate qualifications for pharmacists supervising approved internship programs.

(5) The board shall issue certificates of internship which shall be valid for six (6) years from date of issuance. The fee for a certificate shall be set by administrative regulation of the board, not to exceed fifty dollars (\$50).

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 113, sec. 17, effective June 24, 2015. -- Amended 1996 Ky. Acts ch. 257, sec. 8, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 443, sec. 23, effective July 13, 1990. -- Amended 1982 Ky. Acts ch. 191, sec. 6, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 120, sec. 8; and ch. 221, sec. 4. -- Amended 1946 Ky. Acts ch. 161, sec. 1. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2625.

### **315.060 Examination fee.**

A reasonable examination fee shall be fixed by administrative regulation of the board, not to exceed three hundred dollars (\$300) or increase more than twenty-five dollars (\$25) per year, and shall be collected for each examination taken by an applicant.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 9, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 7, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 2. -- Amended 1970 Ky. Acts ch. 221, sec. 5. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2625.

### **315.065 Continuing education requirements.**

(1) Because of the continuous introduction of new therapeutic and diagnostic agents and changing concepts in the practice of pharmacy, it is essential that a pharmacist undertake a program of continuing education to maintain his professional competency to practice in the public interest.

(2) No pharmacist's license shall be renewed until the license holder is able to submit written proof to the board that he has satisfactorily completed, in the previous renewal period, a continuing education program acceptable to the board. Such continuing education requirements shall be determined by regulation of the board, but they shall not require more than an average of one and one-half (1-1/2) continuing education units (CEU) per year.

(3) The board shall adopt rules and regulations to carry out the provisions of this section, to include guidelines and criteria for reviewing and approving continuing education programs.

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 113, sec. 18, effective June 24, 2015. -- Amended 2001 Ky. Acts ch. 61, sec. 11, effective June 21, 2001. -- Amended 1998 Ky. Acts ch. 531, sec. 4, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 10, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 443, sec. 10, effective July 13, 1990. -- Created 1982 Ky. Acts ch. 191, sec. 9, effective July 15, 1982.

### **315.110 License expiration date -- Renewal fee -- Application and requirements -- Certificate -- Display -- Pocket certificate.**

(1) Each license to practice pharmacy, unless sooner suspended or revoked, shall expire on February 28 following its date of issuance. Every pharmacist who desires to continue to practice pharmacy shall pay to the executive director of the board a reasonable renewal fee



to be set by administrative regulation of the board, but not to exceed one hundred seventy-five dollars (\$175) annually or increase more than twenty-five dollars (\$25) per year, and shall file with the board an application in such form and containing such data as the board may require for renewal of the license. A delinquent renewal penalty fee not to exceed the renewal fee may be assessed and set by administrative regulation for each renewal period the licensee fails to renew the license after expiration.

(2) Every pharmacist shall keep his current certificate conspicuously displayed in his primary place of practice.

(3) In addition to a current renewal certificate, each pharmacist shall be issued upon renewal a pocket certificate which shall be in the licensee's possession at all times when the licensee is engaged in the practice of pharmacy and which shall be exhibited by the licensee upon request from any member, inspector or agent of the board.

**Effective:** June 20, 2005

**History:** Amended 2005 Ky. Acts ch. 61, sec. 2, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 11, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 8, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 3. -- Amended 1970 Ky. Acts ch. 221, sec. 7. -- Amended 1966 Ky. Acts ch. 260, sec. 2. -- Created 1960 Ky. Acts ch. 234, sec. 2. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

### **315.115 Renewal fees suspended for persons in Armed Forces.**

All persons who are required to pay renewal fees to the board as registered pharmacists shall not be required to pay such fees during the time such persons are actively serving in the Armed Forces of the United States.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 12, effective July 15, 1996. -- Amended 1970 Ky. Acts ch. 221, sec. 8. -- Created 1942 Ky. Acts ch. 98, sec. 2.

### **315.120 Notification of failure to renew license -- Procedure for renewal of expired license -- Renewal after lapse of five or more years -- Inactive license.**

(1) Within thirty (30) days after the renewal period, the executive director shall notify all pharmacists who have failed to comply with license renewal requirements.

(2) Any pharmacist who has failed to timely renew his license for any consecutive period up to five (5) years may renew his license only upon satisfying the continuing education regulations of the board and paying the cumulative penalty and renewal fees provided for in KRS 315.110.

(3) Any pharmacist who has failed to timely renew his license for five (5) or more consecutive years may renew his license only upon satisfying the continuing education regulations of the board, passing a satisfactory examination before the board and paying the renewal and penalty fees provided for in KRS 315.110.

(4) Any pharmacist not currently holding an active pharmacist's license in another jurisdiction who does not desire to meet the qualifications for active license renewal shall, upon application, be issued an inactive license. Such license shall entitle the license holder to use the term "pharmacist" but the license holder shall not be permitted to engage in the practice of pharmacy. An inactive license holder may apply for an active license as provided for by the regulations of the board. The inactive license renewal fee shall be set by administrative regulation of the board, not to exceed fifty dollars (\$50) annually.

**Effective:** June 20, 2005

**History:** Amended 2005 Ky. Acts ch. 61, sec. 3, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 13, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 10, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 9. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

**315.121 Grounds for acting against licensee -- Notification to board of conviction required -- Petition for reinstatement -- Expungement.**

(1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:

- (a) Unprofessional or unethical conduct;
- (b) Mental or physical incapacity that prevents the licensee, permit holder, or certificate holder from engaging or assisting in the practice of pharmacy, the wholesale distribution or manufacturing of drugs, or the provision of home medical equipment and services with reasonable skill, competence, and safety to the public;
- (c) Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea, one (1) or more or the following:
  - 1. A felony;
  - 2. An act involving moral turpitude or gross immorality; or
  - 3. A violation of the pharmacy, drug, or home medical equipment laws, rules, or administrative regulations of this state, any other state, or the federal government;
- (d) Knowing or having reason to know that a pharmacist, pharmacist intern, pharmacy technician, or home medical equipment and services provider is incapable of engaging or assisting in the practice of pharmacy or providing home medical equipment and services with reasonable skill, competence, and safety to the public and failing to report any relevant information to the board;
- (e) Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate;
- (f) Engaging in fraud in connection with the practice of pharmacy, the wholesale distribution or manufacturing of drugs, or the provision of home medical equipment and services;
- (g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy or the provision of home medical equipment and services without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," "home medical equipment and services provider," "provider," or other term which might imply that the individual is a pharmacist, pharmacist intern, pharmacy technician, or home medical equipment and services provider;
- (h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;
- (i) Violation of any order issued by the board to comply with any applicable law or administrative regulation;
- (j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution

of legend medications, and failing to report any relevant information to the board;  
or  
(k) Failure to notify the board within fourteen (14) days of a change in one's home address.

(2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician:

- (a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;
- (b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:
  - 1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
  - 2. Certified or licensed health-care personnel who are responsible for care of the patient;
  - 3. Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A;
  - 4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
  - 5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;
- (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of their intended use in illegal activities;
- (d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;
- (e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;
- (f) Except as provided in KRS 315.500, selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;
- (g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;
- (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
- (i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care; or
- (j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

(3) Unprofessional or unethical conduct includes but is not limited to the following acts of a home medical equipment and services provider:

- (a) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a sick or disabled person, or engaging in conduct which substantially departs from accepted standards of providing home medical equipment and services ordinarily exercised by a home medical equipment and services provider, with or without established proof of actual injury;
- (b) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;
- (c) Obtaining any remuneration by fraud, misrepresentation, or deception;
- (d) Providing home medical equipment and services that carry a legend or require a prescription without a medical order from a licensed health care practitioner; or
- (e) Willfully or knowingly failing to maintain complete and accurate records of home medical equipment and services provided in compliance with federal and state laws, rules, or administrative regulations.

(4) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.

(5) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy or to provide home medical equipment and services with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.

(6) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.

(7) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.

- (a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.
- (b) No person may have his or her record expunged under this section more than once. The board shall promulgate administrative regulations under KRS Chapter 13A

to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; assist in the practice of pharmacy; provide home medical equipment and services; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person; or create a significant threat of such harm.

**Effective:** July 12, 2012

**History:** Amended 2012 Ky. Acts ch. 73, sec. 11, effective July 12, 2012. -- Amended 2010 Ky. Acts ch. 22, sec. 7, effective July 15, 2010. -- Amended 2008 Ky. Acts ch. 148, sec. 8, effective July 15, 2008. -- Amended 2005 Ky. Acts ch. 99, sec. 598, effective June 20, 2005. -- Amended 2003 Ky. Acts ch. 51, sec. 4, effective June 24, 2003. -- Amended 2002 Ky. Acts ch. 335, sec. 1, effective July 15, 2002. -- Amended 1998 Ky. Acts ch. 426, sec. 549, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 14, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 11, effective July 15, 1982.

**Legislative Research Commission Note (7/12/2012).** Under the authority of KRS 7.136(1), the Reviser of Statutes has corrected manifest clerical or typographical errors in this statute during codification. The meaning of the text was not changed.

### **315.125 Mental or physical examination ordered by board -- Effect of failure to submit to examination.**

(1) When the board has probable cause to believe a pharmacist, pharmacy technician, licensee, certificate holder, or permit holder is suffering from a mental or physical condition that might impede that person's ability to practice competently, the board may order the individual to undergo a mental or physical examination by an appropriately-trained professional designated by the board.

(2) Failure of a pharmacist, pharmacy technician, licensee, or permit holder to submit to such an examination when directed, unless the failure was due to circumstances beyond his or her control, shall constitute an admission that he or she has developed such a mental or physical disability, or other condition, that continued practice is dangerous to patients or to the public. Failure to attend the examination shall constitute a default, and a final order suspending, limiting, restricting, or revoking the license or permit may be entered without the taking of testimony or presentation of evidence.

(3) A pharmacist, pharmacy technician, licensee, or permit holder whose license has been suspended, limited, restricted, or revoked pursuant to this section shall at reasonable intervals be afforded an opportunity, pursuant to KRS 315.121(5), to demonstrate that he can resume the competent practice of pharmacy or the provision of home medical equipment or services with reasonable skill and safety to patients.

**Effective:** July 12, 2012

**History:** Amended 2012 Ky. Acts ch. 73, sec. 12, effective July 12, 2012. -- Amended 2008 Ky. Acts ch. 148, sec. 5, effective July 15, 2008. -- Created 1996 Ky. Acts ch. 257, sec. 15, effective July 15, 1996.

**Legislative Research Commission Note (7/12/2012).** Under the authority of KRS 7.136(1), the Reviser of Statutes has corrected manifest clerical or typographical errors in this statute during codification. The meaning of the text was not changed.

### **315.126 Pharmacist recovery network committee -- Administrative regulations -- Assessment -- Confidentiality -- Reporting restrictions.**

(1) The board shall establish a pharmacist recovery network committee to promote the early identification, intervention, treatment, and rehabilitation of pharmacists and pharmacist interns who may be impaired by reason of illness, alcohol or drug abuse, or as a result of any other physical or mental condition.

(2) The board may enter into a contractual agreement with a nonprofit corporation, pharmacy professional organization, or similar organization for the purpose of creating,

supporting, and maintaining a pharmacist recovery network committee.

(3) The board may promulgate administrative regulations pursuant to KRS Chapter 13A to effectuate and implement the provisions of this section.

(4) Beginning July 15, 1998, the board shall collect an assessment of ten dollars (\$10) to be added to each licensure renewal application fee payable to the board. This assessment shall be expended by the board on the operation of the pharmacist recovery network committee.

(5) Members of a pharmacist recovery network committee, any administrator, staff member, consultant, agent, volunteer, or employee of the committee acting within the scope of his or her duties and without actual malice and all other persons who furnish information to the committee in good faith and without actual malice shall not be liable for any claim or damages as a result of any statement, decision, opinion, investigation, or action taken by the committee or by any individual member of the committee.

(6) All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the pharmacist recovery network committee, all communications to or from the committee, and all proceedings, findings, and conclusions of the committee, including those relating to intervention, treatment, or rehabilitation, that in any way pertain or refer to a pharmacist or pharmacist intern who is or may be impaired shall be privileged and confidential.

(7) All records and proceedings of the committee that pertain or refer to a pharmacist or pharmacist intern who is or may be impaired shall be privileged and confidential, used by the committee and its members only in the exercise of the proper function of the committee, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings, except as described in subsection (8) of this section.

(8) The committee may only disclose the information relative to an impaired pharmacist or pharmacist intern if:

(a) It is essential to disclose the information to persons or organizations needing the information in order to address the intervention, treatment, or rehabilitation needs of the impaired pharmacist or pharmacist intern;

(b) The release is authorized in writing by the impaired pharmacist or pharmacist intern; or

(c) The committee is required to make a report to the board pursuant to KRS 315.121.

**Effective:** June 20, 2005

**History:** Amended 2005 Ky. Acts ch. 61, sec. 5, effective June 20, 2005. -- Created 1998 Ky. Acts ch. 531, sec. 1, effective July 15, 1998.

**315.131 Proceedings before fine, probation, suspension, revocation of license, permit, or certificate -- Appeals -- Emergency suspension prior to disciplinary hearing.**

(1) Every proceeding imposing a fine or for probation, suspension, or revocation of a license, permit, or certificate issued pursuant to this chapter shall be conducted in accordance with KRS Chapter 13B. Upon failure of the licensee, permit holder, or certificate holder to respond to the complaint at or before the time of the hearing, the allegations set forth in

the complaint shall be taken by the board as confessed.

(2) All decisions revoking or suspending a license, permit, or certificate or placing a licensee, permit holder, or certificate holder on probation or imposing a fine shall be made by the board.

(3) The board may when in its opinion the continued practice of the licensee or certificate holder or the continued operation of the permit holder would be dangerous to the health, welfare, and safety of the general public, issue an emergency order as provided in KRS 13B.125.

(4) A licensee, permit holder, or certificate holder aggrieved by a final order of the board may within ten (10) days after notice thereof move the board to reconsider this order. A motion to reconsider based on newly-discovered material evidence must be made within one (1) year of the entry of the order.

(5) A licensee, permit holder, or certificate holder aggrieved by a final order of the board may appeal to the Franklin Circuit Court in accordance with KRS Chapter 13B.

(6) The board may, without benefit of a hearing, temporarily suspend a license, certificate, or permit for not more than sixty (60) days if the president of the board finds on the basis of reasonable evidence that a licensee, certificate holder, or permit holder:

- (a) Has violated a statute or administrative regulation the board is empowered to enforce, and continued practice or operation by the licensee, certificate holder, or permit holder would create imminent risk of harm to the public; or
- (b) Suffers a mental or physical condition that through continued practice or operation could create an imminent risk of harm to the public.

The emergency suspension shall take effect upon receipt by the licensee, certificate holder, or permit holder of written notice, delivered by certified mail or in person, specifying the statute or administrative regulation violated. At the time the emergency suspension order issues, the board shall schedule a disciplinary hearing to be held in accordance with the provisions of KRS Chapter 13B within sixty (60) days thereafter.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 16, effective July 15, 1996; and ch. 318, sec. 271, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 12, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 8.

**Legislative Research Commission Note** (10/16/96). The initial 1996 codification of the amendments to this statute from the 1996 Regular Session has been revised with respect to subsection (5) of the statute. 1996 Ky. Acts ch. 257, sec. 16, made the venue for appeals "the Franklin Circuit Court" while 1996 Ky. Acts ch. 318, sec. 271, changed "permittee" to "permit holder," in existing language that set the venue for appeals as "the Circuit Court of the county in which the licensee, permittee or certificate holder conducts his practice or place of business." The changing of the word "permittee" to "permit holder" in this phrase was purely stylistic. Therefore, although Acts ch. 318 was a later enactment than Acts ch. 257 for purposes of KRS 446.250, the substantive amendment on this point in Acts ch. 257 prevails over the nonsubstantive, stylistic amendment in Acts ch. 318 pursuant to 1996 Ky. Acts ch. 318, sec. 358. The text of subsection (5) has been altered to reflect this determination.

**Legislative Research Commission Note** (7/15/96). This section was amended by 1996 Ky. Acts chs. 257 and 318. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts ch. 318, which was last enacted by the General Assembly, prevails under KRS 446.250.

### **315.135 Registration as pharmacy technician required to assist in the practice of pharmacy -- Exemptions.**

(1) Effective April 1, 2009, a person shall not assist in the practice of pharmacy unless he or she is duly registered as a pharmacy technician under the provisions of this chapter or is

exempt under subsection (2) of this section.

(2) A person may assist in the practice of pharmacy without obtaining the registration required by this section if the person:

- (a) Has filed an application with the board in accordance with KRS 315.136 and no more than thirty (30) days has elapsed since the date the applicant was first employed by the pharmacy. The exemption shall not apply if:
  - 1. The application has been denied;
  - 2. The person is less than sixteen (16) years of age; or
  - 3. The person has previously been denied a registration or has had a registration revoked or suspended in any jurisdiction and the registration has not yet been issued or reinstated;
- (b) Is in the employ of a son, daughter, spouse, parent, or legal guardian; or
- (c) Is participating in a work-study program through an accredited secondary or postsecondary educational institution.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 148, sec. 1, effective July 15, 2008.

### **315.136 Requirements for registration as pharmacy technician.**

(1) Every applicant for registration as a pharmacy technician shall be sixteen (16) years of age and of good mental health and moral character and shall file with the board an application in such form and containing such data as the board may reasonably require.

(2) The application fee shall be twenty-five dollars (\$25). All applicants for registration as a pharmacy technician who serve only on a voluntary basis as a pharmacy technician with a pharmacy operated by a charitable provider as defined in KRS 142.301 shall not be required to pay the application fee.

(3) The board shall issue a certificate of registration and a pocket registration card to an applicant who meets the requirements for registration.

**Effective:** July 15, 2010

**History:** Amended 2010 Ky. Acts ch. 11, sec. 1, effective July 15, 2010. -- Created 2008 Ky. Acts ch. 148, sec. 2, effective July 15, 2008.

### **315.137 Denial of application for registration as pharmacy technician -- Hearing.**

(1) The board may deny an application for registration filed under KRS 315.136 if the applicant:

- (a) Submits an incomplete application;
- (b) Fails to submit the application fee; or
- (c) Violates or is deemed to be in violation of any of the provisions of KRS 315.121.

(2) After denying an application for registration, the board shall set the matter for a hearing in accordance with KRS Chapter 13B, upon the written request of the applicant. The applicant's request shall be submitted to the board no later than thirty (30) days immediately following the date the letter of denial is postmarked.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 148, sec. 3, effective July 15, 2008.

### **315.138 Renewal of registration as pharmacy technician -- Display of registration certificate.**

(1) Every pharmacy technician who wishes to renew his or her registration shall pay to the executive director of the board an annual renewal fee of twenty-five dollars (\$25) and shall



file with the board an application in such form and containing such information that the board reasonably determines necessary to renew the registration. Each pharmacy technician's registration shall expire on March 31 of each year. A delinquent renewal penalty fee not to exceed twenty-five dollars (\$25) may be assessed for each renewal period the registrant fails to remove his or her registration after the expiration of the registration.

(2) Every pharmacy technician shall keep his or her current certificate of registration conspicuously displayed in the technician's primary place of employment.

(3) In addition to a current certificate of registration, each pharmacy technician shall be issued, upon renewal, a pocket registration card which shall be in the registrant's possession when the registrant is assisting in the practice of pharmacy. The pocket registration card shall be exhibited upon the request of any member, inspector, or agent of the board.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 148, sec. 4, effective July 15, 2008.

### **315.150 Board membership -- Appointment -- Term -- Vacancy -- Oath -- Quorum.**

(1) The board shall consist of six (6) members appointed by the Governor. Five (5) members shall be pharmacists licensed in this state. One (1) member shall be a citizen at large, who is not associated with or financially interested in the practice of pharmacy.

(2) In any calendar year scheduled to be the last full calendar year of a member's regular term in office, the association shall select and submit to the Governor a list of five (5) pharmacists, each of whom has had at least five (5) years' experience in the practice of pharmacy, is a resident of the state and in good standing with the board. On or before March 1 of the same year, the society, other state pharmacy organizations, or individuals may submit recommendations to the association for its consideration in selecting the list to be submitted. The Governor shall, before October 1 of the same year, appoint no more than two (2) persons from each list so submitted, to take office on January 1 following. The citizen member shall be appointed by the Governor. No two (2) pharmacist members of the board shall be residents of the same county.

(3) Beginning January 1, 2005, the term of each board member shall be four (4) years. Each member shall serve until his or her successor is appointed and qualified, unless removed for cause. No member shall be appointed to serve for more than two (2) full terms.

(4) The Governor shall fill any vacancy of a pharmacist member from the names last submitted within sixty (60) days after such a vacancy occurs. Any member so appointed shall commence service at the next regularly-scheduled board meeting and shall serve for the remainder of the term vacated.

(5) Each member shall take and subscribe to an oath before a competent officer to perform the duties of the office faithfully and impartially. The oath shall be inscribed upon the member's commission.

(6) Four (4) members of the board shall constitute a quorum.

**Effective:** July 13, 2004

**History:** Amended 2004 Ky. Acts ch. 96, sec. 4, effective July 13, 2004. -- Amended 1996 Ky. Acts ch. 257, sec. 17, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 13, effective July 15, 1982. -- Amended 1976 Ky. Acts ch. 206, sec. 8. -- Amended 1970

### **315.155 Removal of board members.**

(1) The Governor may remove a member of the board for any of the following reasons:

- (a) Refusal or inability of a board member to perform his duties as a member of the board in an efficient, responsible and professional manner;
- (b) Misuse of the office by a member of the board to obtain personal, pecuniary, or material gain or advantage for himself or another;
- (c) Willful violation of any provision of KRS Chapter 315 or any rule or regulation promulgated thereunder.

(2) Any person may file a complaint with the executive director of the board against a board member alleging specific facts which constitute grounds for removal from the board. The executive director shall transmit a copy of any such complaint to the Governor, the president of the board and the accused board member. Upon a written recommendation of the Governor or two-thirds (2/3) of the members of the board, a hearing shall be conducted before an impartial hearing officer pursuant to KRS Chapter 13B.

(3) The hearing officer shall submit a transcript of the hearing to the Governor with a recommendation based on evidence presented in the hearing. The Governor shall review the transcript to determine if the evidence supports the recommendation, and he shall enter a finding in accordance with such determination.

(4) In the event a board member is removed, his removal shall be effective as of the date of the Governor's finding and a vacancy shall be deemed to exist. Any board member so removed shall be entitled to appeal the removal in the Franklin Circuit Court.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 18, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 19, effective July 15, 1982.

### **315.160 Election of officers -- Executive director -- Meetings.**

(1) The board shall elect annually from its membership a president and such other officers as it deems necessary. These officers shall serve for a term of one (1) year and perform the duties prescribed by the board. No officer shall serve more than two (2) consecutive full terms in each office to which he is elected.

(2) The board shall employ a pharmacist to serve as a full time employee of the board in the position of executive director. The executive director shall be responsible for the performance of the administrative functions of the board and such other duties as the board may direct. The board may employ, upon recommendation of the executive director, such additional assistance as necessary for the proper conduct of board business and in accordance with the rules and regulations of the Kentucky Personnel Cabinet.

(3) The board shall meet at least four (4) times a year to transact business, at such place as it may determine. The board may also meet at the call of the president or a majority of the board members. Each board member shall be given adequate prior notice of any board meeting.

**Effective:** July 15, 1998

**History:** Amended 1998 Ky. Acts ch. 154, sec. 89, effective July 15, 1998. -- Amended 1982 Ky. Acts ch. 191, sec. 14, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 13. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2622.

### **315.171 Compensation of board members and executive director.**

(1) Beginning January 1, 1998, each member of the board shall receive not more than one hundred dollars (\$100) for each day actively engaged in the service of the board. During the period between July 15, 1996, and January 1, 1998, each board member shall receive not more than seventy-five dollars (\$75) for each day actively engaged in the service of the board. Each member shall receive his traveling expenses and all necessary expenses incurred in the performance of his official duties.

(2) The executive director of the board shall receive a reasonable salary determined by the board. He shall also receive his traveling expenses and all necessary expenses incurred in the performance of his official duties.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 19, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 15, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 5.

### **315.180 Executive director to keep record of persons issued licenses, permits or certificates.**

The executive director shall keep a register of the names of those persons to whom a license, permit or certificate has been issued and the dates thereof.

**Effective:** July 15, 1982

**History:** Amended 1982 Ky. Acts ch. 191, sec. 16, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 15. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

### **315.191 Powers and duties of board -- Advisory council.**

(1) The board is authorized to:

- (a) Promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters set forth in this chapter relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, manufacturers, and home medical equipment and services providers, to the extent that regulation and control of same have not been delegated to some other agency of the Commonwealth, but administrative regulations relating to drugs and home medical equipment and services shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order or home medical equipment sold pursuant to a medical order. However, nothing contained in this chapter shall be construed as authorizing the board to promulgate any administrative regulations relating to prices or fees or to advertising or the promotion of the sales or use of commodities or services;
- (b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to schedule and conduct hearings on behalf of the board on any matter under the jurisdiction of the board;
- (c) Prescribe the time, place, method, manner, scope, and subjects of examinations, with at least two (2) examinations to be held annually;
- (d) Issue and renew all:
  1. Licenses for home medical equipment and services providers engaged in providing home medical equipment and services; and

2. Licenses, certificates, and permits for all pharmacists, pharmacist interns, pharmacies, pharmacy technicians, wholesale distributors, and manufacturers engaged in the manufacture, distribution, or dispensation of drugs;
- (e) Investigate all complaints or violations of the state pharmacy and home medical equipment laws and the administrative regulations promulgated by the board, and bring all these cases to the notice of the proper law enforcement authorities;
- (f) Promulgate administrative regulations, pursuant to KRS Chapter 13A, that are necessary and to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between pharmacists and pharmacies licensed or issued a permit by it;
- (g) Perform all other functions necessary to carry out the provisions of law and the administrative regulations promulgated by the board relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, manufacturers, and home medical equipment and services providers;
- (h) Establish or approve programs for training, qualifications, and registration of pharmacist interns;
- (i) Assess reasonable fees, in addition to the fees specifically provided for in this chapter and consistent with KRS 61.870 to 61.884, for services rendered to perform its duties and responsibilities, including, but not limited to, the following:
  1. Issuance of duplicate certificates;
  2. Mailing lists or reports of data maintained by the board;
  3. Copies of documents; or
  4. Notices of meetings;
- (j) Seize any drug or device found by the board to constitute an imminent danger to public health and welfare;
- (k) Establish an advisory council to advise the board on administrative regulations and other matters, within the discretion of the board, pertinent to the regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug distribution, drug manufacturing, and home medical equipment and services. The council shall consist of nine (9) members selected by the board for terms of up to four (4) years. No member shall serve on the council for more than eight (8) years. Membership of the council shall include seven (7) individuals broadly representative of the profession of pharmacy and the general public, and two (2) individuals representative of the home medical equipment and services profession licensed in accordance with KRS 315.518. Members shall be selected by the board from a list of qualified candidates submitted by the association, society, or other interested parties;
- (l) Promulgate administrative regulations establishing the qualifications that pharmacy technicians are required to attain prior to engaging in pharmacy practice activities outside the immediate supervision of a pharmacist; and
- (m) Oversee and administer the licensure of home medical equipment and services providers pursuant to KRS 315.510 to 315.524.

(2) The board shall have other authority as may be necessary to enforce pharmacy and home medical equipment laws and administrative regulations of the board including, but not limited to:

- (a) Joining or participating in professional organizations and associations organized exclusively to promote improvement of the standards of practice of pharmacy and

of providing home medical equipment and services for the protection of public health and welfare or facilitate the activities of the board; and  
(b) Receiving and expending funds, in addition to its biennial appropriation, received from parties other than the state, if:

1. The funds are awarded for the pursuit of a specific objective which the board is authorized to enforce through this chapter, or which the board is qualified to pursue by reason of its jurisdiction or professional expertise;
2. The funds are expended for the objective for which they were awarded;
3. The activities connected with or occasioned by the expenditure of the funds do not interfere with the performance of the board's responsibilities and do not conflict with the exercise of its statutory powers;
4. The funds are kept in a separate account and not commingled with funds received from the state; and
5. Periodic accountings of the funds are maintained at the board office for inspection or review.

(3) In addition to the sanctions provided in KRS 315.121, the board or its hearing officer may direct any licensee, permit holder, or certificate holder found guilty of a charge involving home medical equipment, pharmacy, or drug laws, rules, or administrative regulations of the state, any other state, or federal government, to pay to the board a sum not to exceed the reasonable costs of investigation and prosecution of the case, not to exceed twenty-five thousand dollars (\$25,000).

(4) In an action for recovery of costs, proof of the board's order shall be conclusive proof of the validity of the order of payment and any terms for payment.

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 56, sec. 3, effective June 24, 2015. -- Amended 2012 Ky. Acts ch. 73, sec. 13, effective July 12, 2012. -- Amended 2008 Ky. Acts ch. 148, sec. 10, effective July 15, 2008. -- Amended 2005 Ky. Acts ch. 61, sec. 4, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 20, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 17, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 16. -- Created 1966 Ky. Acts ch. 260, sec. 1.

**Legislative Research Commission Note** (7/12/2012). The internal format of subsection (1)(d) of this statute has been modified by the Reviser of Statutes from the way it appeared in 2012 Ky. Acts ch. 73, sec. 13, under the authority of KRS 7.136(1). The words in the text were not changed.

### **315.192 Board of Pharmacy not to prohibit sale and dispensing of laetrile.**

The Kentucky Board of Pharmacy shall make no rule or regulation which would prohibit the sale and dispensing of amygdalin (laetrile) by a duly licensed pharmacist.

**Effective:** July 15, 1980

**History:** Created 1980 Ky. Acts ch. 354, sec. 10, effective July 15, 1980.

### **315.193 Board members' immunity for official acts.**

(1) Members of the board, its agents, and employees shall be immune from suit in any action, civil, or criminal, which is based upon any official act or acts performed by them in good faith.

(2) Any pharmacist, whose duty it is to review or evaluate the acts of other pharmacists and who serves on any committee, board, commission or other entity affiliated with a governmental or quasi-governmental agency or with a medical facility, shall not be required to respond in damages for any official action taken by him in good faith as a member thereof.

**Effective:** July 15, 1996

**History:** Amended 1996 Ky. Acts ch. 257, sec. 21, effective July 15, 1996. -- Created 1974 Ky. Acts ch. 310, sec. 4.

**315.195 Agency fund -- Use.**

(1) All license, permit, and certificate fees, charges, fines, and other moneys collected by the board under the provisions of this chapter, and the administrative regulations of the board, shall be deposited into the State Treasury and credited to a trust and agency fund to be used by the board in carrying out the provisions of this chapter, and are hereby appropriated for those purposes.

(2) Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the fiscal year shall not lapse but shall be carried forward into the succeeding fiscal year.

**Effective:** July 12, 2012

**History:** Amended 2012 Ky. Acts ch. 73, sec. 14, effective July 12, 2012. -- Amended 1996 Ky. Acts ch. 257, sec. 22, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 18, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 11.

**2012-2014 Budget Reference.** See State/Executive Branch Budget, 2012 Ky. Acts ch. 144, Pt. V, A, 10 at 1244.

**315.200 For whom prescriptions to be refilled.**

No prescription shall be knowingly refilled except for the person for whom it was written.

**Effective:** October 1, 1942

**History:** Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2060a-6.

**315.205 Notification of immunization to minor's primary care provider.**

Upon the request of an individual or his or her parent or guardian, a pharmacist who administers an immunization to an individual who is fourteen (14) to seventeen (17) years of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of age, as authorized in KRS 315.010(19), shall provide notification of the immunization to the individual's primary care provider.

**Effective:** June 8, 2011

**History:** Amended 2011 Ky. Acts ch. 81, sec. 2, effective June 8, 2011. -- Created 2010 Ky. Acts ch. 37, sec. 2, effective July 15, 2010.

**315.210 Reciprocity.**

The board may exchange license certificates with other states so as to allow registered pharmacists of other states to practice pharmacy in this state under regulations prescribed by the board.

**History:** Amended 1970 Ky. Acts ch. 221, sec. 17. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2619a-1.

**315.220 Powers of representatives of board.**

(1) For the purpose of enforcing the provisions of this chapter, officers, agents, and inspectors of the board shall have the power and authority to:

(a) Administer oaths;

(b) Enter upon premises of all facilities issued a permit or license by the board, at all reasonable times for the purpose of:

1. Making inspections and carrying out the provisions of this chapter;
2. Conducting investigations;
3. Requiring production of books, papers, documents, records, or other evidence for inspection or copying;
4. Seizing evidence; or
5. Securing oral or written statements;

(c) Employ special investigators;

(d) Expend funds for the purpose of obtaining evidence; and

(e) Issue subpoenas.

(2) As used in subsection (1) of this section, "records" includes, but is not limited to, patient records.

(3) Any decision to inspect, copy, or seize books, papers, documents, records, or other evidence shall be at the discretion of the officer, agent, or inspector of the board.

(4) Inspection, copying, or seizure of books, papers, documents, records, or other evidence does not affect the confidential nature of those records, and the board shall maintain the records so as to protect the confidentiality of the records.

**Effective:** July 12, 2012

**History:** Amended 2012 Ky. Acts ch. 73, sec. 15, effective July 12, 2012. -- Amended 1996 Ky. Acts ch. 257, sec. 23, effective July 15, 1996. -- Created 1966 Ky. Acts ch. 260, sec. 9.

### **315.230 Restraint of violations -- Legal representation.**

(1) Notwithstanding the existence or pursuit of any other remedy (civil or criminal) the board is hereby authorized to institute and maintain actions to restrain and enjoin any violation of this chapter, or the rules and regulations of the board.

(2) City, county and Commonwealth's attorneys, and the Attorney General, shall within their respective jurisdictions represent the board, its officers, agents, and inspectors, in the enforcement of the provisions of this chapter, and the rules and regulations of the board, but when the board deems it necessary, it may employ at its discretion, special attorneys to assist the board, or its officers, agents, or inspectors, and may pay reasonable compensation, fees and other costs from any unexpended funds.

**History:** Created 1966 Ky. Acts ch. 260, sec. 10.

### **315.235 Attorney General's jurisdiction to investigate and prosecute violators of pharmacy laws.**

(1) The Attorney General has concurrent jurisdiction with the Commonwealth's attorneys of this state for the enforcement of the provisions of this chapter.

(2) The Attorney General may investigate and prosecute a practitioner or any other person who violates the provisions of:

(a) This chapter; and

(b) Any other statute if the violation is committed by the practitioner or person in the course of committing a violation described in paragraph (a) of this subsection.

(3) When acting pursuant to this section, the Attorney General may commence his investigation and file a criminal action without leave of court, and the Attorney General has exclusive charge of the conduct of the prosecution.

**Effective:** June 20, 2005

**History:** Created 2005 Ky. Acts ch. 150, sec. 16, effective June 20, 2005.

### **315.295 Automated pharmacy system in residential hospice facilities.**

(1) As used in this section and KRS 315.300:

(a) "Automated pharmacy system" means a mechanical system that delivers prescribed over-the-counter and legend drugs, and controlled substances received from a pharmacy licensed in Kentucky that maintains transaction information; and

(b) "Residential hospice facility" means a facility licensed under KRS Chapter 216B that provides residential skilled nursing care, pain management, and treatment for

acute and chronic conditions for terminally ill patients.

(2) A pharmacy may provide pharmacy services to a residential hospice facility through the use of an automated pharmacy system under the supervision of a licensed pharmacist pursuant to the policies, procedures, and protocol established by the Kentucky Board of Pharmacy. The supervising pharmacist shall not be required to be physically present at the location of the automated pharmacy system and supervision may be provided electronically.

(3) Drugs stored in bulk or unit dose in an automated pharmacy system in a residential hospice facility shall be considered the inventory of the pharmacy providing services to the facility and drugs delivered through the automated pharmacy system shall be considered dispensed by the pharmacy.

(4) The Kentucky Board of Pharmacy shall promulgate administrative regulations pursuant to KRS Chapter 13A to implement the provisions of this section that shall include but not be limited to:

- (a) Accuracy of the automated pharmacy system;
- (b) Security of the system;
- (c) Recordkeeping, including but not limited to electronic signatures of authorized users;
- (d) Inventory management;
- (e) Labeling or reporting requirements that include identification of the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescriber; and
- (f) Training for authorized users.

(5) Nothing in this section shall be construed to limit or impede pharmacy practice in Kentucky.

**Effective:** July 12, 2006

**History:** Created 2006 Ky. Acts ch. 153, sec. 1, effective July 12, 2006.

**315.300 Placement of drugs by pharmacy with authorized employees of home health agencies and hospices -- Protocol -- Allowable legend drugs -- Administrative regulations.**

(1) A pharmacy shall be allowed to place drugs with a home health agency's authorized employees and with a hospice's authorized employees for the betterment of public health. The pharmacy shall remain the legal owner of the drugs.

(2) A written agreement between the pharmacy and home health agency or hospice shall document the protocol for the handling and storage of the drugs by authorized employees and shall be approved by the pharmacist in charge.

(3) The pharmacist in charge shall review the protocol to assure that safe, secure and accountable handling of controlled legend drugs is maintained under the protocol before giving approval.

(4) The pharmacist in charge or a pharmacist designee shall physically inspect and review the drug storage and handling at the home health agency and the hospice not less than



annually.

(5) The home health agency and the hospice protocol shall include but not be limited to the following:

- (a) Safe and secure storage of drugs;
- (b) Access to drugs limited to authorized employees;
- (c) Records of drugs checked out to authorized employees and records of drugs, amounts, and to whom and by whom administered;
- (d) Prompt notification of the pharmacy when a drug is used, including the prescriber, patient, drug, dosage form, directions for use and other pertinent information;
- (e) Billing information;
- (f) Procedures for handling drugs beyond their expiration date; and
- (g) Inventory control.

(6) The following legend drugs shall be allowed under these agreements:

- (a) Sterile water for injection or irrigation;
- (b) Sterile saline solution for injection or irrigation;
- (c) Heparin flush solution;
- (d) Diphenhydramine injectable;
- (e) Epinephrine injectable;
- (f) Glucagon;
- (g) Influenza vaccine; and
- (h) Pneumonia vaccine.

(7) As used in this section:

- (a) "Authorized employee" means any employee of a home health agency or hospice who, in the course of the employee's duties, is licensed by the employee's appropriate licensing agency to administer legend drugs;
- (b) "Home health agency" means an entity required to be licensed under KRS Chapter 216; and
- (c) "Hospice" means an entity authorized to hold itself out to the public as a hospice or as a licensed hospice pursuant to KRS Chapter 216.

(8) The cabinet shall promulgate administrative regulations to implement the provisions of this section.

(9) Nothing in this section shall preclude or prevent a pharmacy from providing pharmacy services through an automated pharmacy system to a residential hospice facility in accordance with KRS 315.295.

**Effective:** July 12, 2006

**History:** Amended 2006 Ky. Acts ch. 153, sec. 2, effective July 12, 2006. -- Created 1998 Ky. Acts ch. 531, sec. 5, effective July 15, 1998.

**315.310 Duty of treating pharmacist utilizing telehealth to ensure patient's informed consent and maintain confidentiality -- Board to promulgate administrative regulations -- Definition of "telehealth".**

(1) A treating pharmacist who provides or facilitates the use of telehealth shall ensure:

- (a) That the informed consent of the patient, or another appropriate person with authority to make the health care treatment decision for the patient, is obtained before services are provided through telehealth; and
- (b) That the confidentiality of the patient's medical information is maintained as required by this chapter and other applicable law. At a minimum, confidentiality shall be maintained through appropriate processes, practices, and technology as designated by the board and that conform to applicable federal law.

(2) The board shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement this section and as necessary to:

- (a) Prevent abuse and fraud through the use of telehealth services;
- (b) Prevent fee-splitting through the use of telehealth services; and
- (c) Utilize telehealth in the provision of pharmacy services and in the provision of continuing education.

(3) For purposes of this section, "telehealth" means the use of interactive audio, video, or other electronic media to deliver health care. It includes the use of electronic media for diagnosis, consultation, treatment, transfer of health or medical data, and continuing education.

**Effective:** July 14, 2000

**History:** Created 2000 Ky. Acts ch. 376, sec. 15, effective July 14, 2000.

**315.320 Illegal operation of out-of-state pharmacy -- Exemption for lapsed license or permit -- Penalty -- Exceptions from section.**

(1) A person or pharmacy is guilty of a Class C felony if the person or pharmacy, located inside or outside this Commonwealth, is not licensed by the Commonwealth of Kentucky to engage in the practice of pharmacy and knowingly:

- (a) Communicates with a person in this Commonwealth; and
- (b) Uses or attempts to use such communication or information, in whole, or in part, to:
  - 1. Fill or refill a prescription for a prescription drug for the other person; or
  - 2. Deliver, cause, allow, or aid in the delivery of a controlled substance, imitation controlled substance, counterfeit substance or prescription drug to the other person.

(2) A person or pharmacy is guilty of a Class B felony if the substance or drug dispensed in subsection (1) of this section:

- (a) Is classified in Schedule I; or
- (b) Proximately causes serious physical injury or the death of the intended recipient of the substance or drug or any other person.

(3) The court shall not grant probation to or suspend the sentence of a person punished pursuant to subsection (2) of this section.

(4) A person who knowingly aids another in any act or transaction that violates the provisions of subsection (1) of this section is guilty of a Class C felony.

(5) A person who knowingly aids another in any act or transaction that violates the provisions of subsection (2) of this section is guilty of a Class B felony.

(6) A person or pharmacy may be prosecuted, convicted, and punished for a violation of this section whether or not the person is prosecuted, convicted, or punished for a violation of any other statute based upon the same act or transaction.

(7) This section shall not apply to a licensed pharmacist or permitted pharmacy that inadvertently allows its license or permit issued by the Kentucky Board of Pharmacy to lapse for a period of less than thirty (30) days.

(8) This section shall not apply to authorized agents of a pharmacy with a valid permit issued by the Kentucky Board of Pharmacy.

(9) This section shall not apply to an authorized agent of a pharmacy that inadvertently allows its permit issued by the Kentucky Board of Pharmacy, to lapse for a period of less than thirty (30) days.

(10) Unless a more specific penalty applies within this chapter, anyone who uses the Internet to communicate and facilitate the sale of controlled substances, except as specifically provided for in this chapter, may be prosecuted under KRS Chapter 218A.

**Effective:** June 26, 2007

**History:** Amended 2007 Ky. Acts ch. 124, sec. 11, effective June 26, 2007. -- Created 2005 Ky. Acts ch. 150, sec. 14, effective June 20, 2005.

### **315.325 Exemption from pharmacy licensing requirements for common carriers transporting drugs.**

The provisions of KRS 315.320 do not apply to a person who is:

(1) A common or contract carrier or warehouseman, or any employee thereof, unless the person is acting outside of the usual course of his business or employment or knows or has reasonable cause to believe that the act or transaction is unlawful; or

(2) An employee or agent of a pharmacist or pharmacy licensed or permitted pursuant to this chapter and acting in accordance with KRS Chapter 218A, unless the person is acting outside of the usual course of his business or employment or knows or has reasonable cause to believe that the act or transaction is unlawful; or

(3) The intended recipient of a substance or drug, unless the intended recipient knows or has reasonable cause to believe that the act or transaction is unlawful.

**Effective:** June 20, 2005

**History:** Created 2005 Ky. Acts ch. 150, sec. 15, effective June 20, 2005.

### **315.330 Seizure and forfeiture of illegal drug shipments.**

(1) Any drug which is ordered or shipped in violation of any provision of this chapter or KRS Chapter 218A shall be considered as contraband and may be seized by any peace officer or any employee of the Board of Pharmacy designated to enforce the provisions of this chapter or KRS Chapter 218A.

(2) The officer, prior to seizing the drug, shall make a reasonable effort to determine:

- (a) The person who ordered the drug;
- (b) The pharmacy from which the drug was ordered;
- (c) The shipper of the drug;

- (d) The intended recipient of the drug; and
- (e) Whether or not the shipment was legal.

(3) Unless the matter is the subject of a criminal prosecution, if, after thirty (30) days of investigation, the officer seizing the drug cannot adequately determine the information required by subsection (2) of this section, the drug that has been seized shall be considered as abandoned and escheat to the Commonwealth.

(4) If a drug seized pursuant to this section is the subject of a criminal investigation, the drug shall be retained as evidence and, if there is a conviction of any person or pharmacy relating to the ordering or shipment of the drug, the drug shall be forfeited to the Commonwealth. If the defendant is found not guilty or the charges are dismissed with prejudice, the drug shall be returned to the defendant.

(5) Drugs which have been seized and which have been forfeited or abandoned and escheat to the Commonwealth shall be destroyed.

**Effective:** June 20, 2005

**History:** Created 2005 Ky. Acts ch. 150, sec. 17, effective June 20, 2005.

### **315.335 Reporting of robbery, theft, or missing shipment of controlled substances.**

(1) A pharmacy located in Kentucky which has a robbery or theft of a controlled substance shall immediately following the robbery or discovery of the theft report the incident to a law enforcement agency serving the geographic area in which the pharmacy is located.

(2) A pharmacy which has mailed or shipped a controlled substance to a location in Kentucky and learns that the mailing or shipment did not arrive shall within three (3) business days report that nonreceipt to:

- (a) The Department of Kentucky State Police; and
- (b) If applicable, the United States Postal Inspection Service.

- (3) (a) The reports required pursuant to subsections (1) and (2) of this section shall contain at a minimum, if known and applicable:
1. The name, National Drug Code, and quantity of each controlled substance involved;
  2. A description of the circumstances of the loss;
  3. The names and contact information of any witnesses; and
  4. The name and description of any person suspected of committing the offense or causing the loss.
- (b) The Board of Pharmacy may by administrative regulation authorize a pharmacy to submit a completed DEA 106 form or a successor form in lieu of the data elements required by this subsection.

**Effective:** March 4, 2013

**History:** Amended 2013 Ky. Acts ch. 2, sec. 5, effective March 4, 2013. – Created 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 11, effective July 20, 2012.

### **315.400 Definitions for KRS 315.400 to 315.412.**

As used in KRS 315.400 to 315.412:

- (1) "Authorized distributor of record" means a wholesale distributor that:
- (a) Has established an ongoing relationship with a manufacturer to distribute the manufacturer's prescription drug. An ongoing relationship exists between a

wholesale distributor and a manufacturer if the wholesale distributor, including any affiliated group of the wholesale distributor as defined in Section 1504 of the Internal Revenue Code, has a written agreement for distribution in effect; and  
(b) Is listed on the manufacturer's current list of authorized distributors of record;

(2) "Co-licensed partner" means two (2) or more entities that have the right to engage in the manufacturing or marketing or both of a prescription drug consistent with the Federal Drug Administration's implementation of the federal Prescription Drug Marketing Act;

(3) "Co-licensed product" means a prescription drug manufactured by two (2) or more co-licensed partners;

(4) "Counterfeit prescription drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed the drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor;

(5) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor, and:

- (a) The wholesale distributor takes title to but not physical possession of the drug;
- (b) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug; and
- (c) The pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug receives delivery directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or an authorized distributor of record;

(6) "Emergency medical reasons" includes but is not limited to:

- (a) Transfers of a prescription drug between health-care entities or between a health-care entity and a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruptions of the regular distribution schedules;
- (b) Sales of drugs for use in the treatment of acutely ill or injured persons to nearby emergency medical services providers, firefighting organizations, or licensed health-care practitioners in the same marketing or service area;
- (c) The provision of emergency supplies of drugs to nearby nursing homes, home health agencies, or hospice organizations for emergency use when necessary drugs cannot be obtained; or
- (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

- (7) "End user" means a patient or consumer that uses a prescription drug as prescribed by an authorized health-care professional;
- (8) "FDA" means the United States Food and Drug Administration and any successor agency;
- (9) "Manufacturer" means the same as defined in KRS 315.010;
- (10) "Manufacturer's exclusive distributor" means a distributor who:
- (a) Contracts with a manufacturer to provide or coordinate the warehousing, distributing, or other similar services on behalf of a manufacturer;
  - (b) Takes title of the prescription drug but does not have responsibility to direct the sale of the manufacturer's prescription drug;
  - (c) Is licensed under KRS 315.402; and
  - (d) Is an authorized distributor of record;
- (11) "Normal distribution channel" means a chain of custody for a prescription drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's third-party logistics provider, or a manufacturer's exclusive distributor that goes directly, by drop shipment or by intracompany transfer, to:
- (a) A pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;
  - (b) A pharmacy warehouse that performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control to a patient, pursuant to a prescription for a patient, or to a person authorized by law to administer a prescription drug for use by a patient;
  - (c) An authorized distributor of record:
    - 1. Then to a pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;
    - 2. Then to a pharmacy warehouse as specified in paragraph (b) of this subsection; or
    - 3. Then to another authorized distributor of record to a licensed health-care facility or pharmacy, or a practitioner authorized by law to distribute a prescription drug to an end user; or
  - (d) A nonprofit organization under state contract to distribute prescription drugs to pharmacies pursuant to the state's emergency response plan and the subsequent distribution of those prescription drugs to pharmacies;
- (12) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug;
- (13) "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control;
- (14) "Prescription drug" means the same as defined in KRS 315.010;

(15) "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, or other entities by receiving, taking inventory, and managing the disposition of outdated or nonsalable drugs;

(16) "Third-party logistics provider" means an entity that contracts with a manufacturer to provide or coordinate the warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the drug or have responsibility to direct the sale of the manufacturer's drug. A third-party logistics provider who is a licensed wholesale distributor under KRS 315.402 and is a manufacturer's authorized distributor of record shall be considered as part of the normal distribution channel;

(17) "Wholesale distribution" means the distribution of a prescription drug to persons other than an end user, but does not include:

- (a) Intracompany sales or transfers;
- (b) The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;
- (c) The distribution of prescription drug samples by a manufacturer or authorized distributor;
- (d) Drug returns or transfers to the original manufacturer, original wholesale distributor, or transfers to a reverse distributor or third-party returns processor;
- (e) The sale, purchase, or trade of a drug pursuant to a prescription;
- (f) The delivery of a prescription drug by a common carrier;
- (g) The purchase or acquisition by a health-care entity or pharmacy that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization, or health-care entities or pharmacies that are members of the group organization;
- (h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable health-care entity to a nonprofit affiliate of the organization as otherwise permitted by law;
- (i) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy with another pharmacy or pharmacies; or
- (j) The distribution of a prescription drug to a health-care practitioner or to another pharmacy if the total number of units transferred during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and

(18) "Wholesale distributor" means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 3, effective July 15, 2008.

### **315.402 Licensure of wholesale distributors of prescription drugs -- Record retention -- Administrative regulations -- Confidentiality.**

(1) A wholesale distributor shall be licensed by the board under this section prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth. Each

license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.

(2) A wholesale distributor shall be required to maintain accurate records of all drugs handled in accordance with KRS 315.400 to 315.412, and records shall be made available to agents of the board for inspection upon request.

(3) Licensing requirements that exceed the requirements of federal law shall not apply to a manufacturer distributing its own FDA-approved drugs or co-licensed products, unless there is reasonable cause to believe that the manufacturer presents a special risk of distributing counterfeit prescription drugs in the Commonwealth.

(4) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(5) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure in conformity with the guidelines for state licensure of a wholesale prescription drug distributor issued by the FDA.

(6) Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 4, effective July 15, 2008.

#### **315.404 Returns or exchanges of prescription drugs.**

(1) (a) A wholesale distributor may receive prescription drug returns or exchanges from a pharmacy, pharmacy warehouse, or other person authorized to distribute a prescription drug to an end user under the terms and conditions of an agreement between the parties.

(b) Returns of expired, damaged, recalled, or otherwise nonsalable prescription drugs shall be distributed by the receiving wholesale distributor only to the original manufacturer, a third-party returns processor, or a reverse distributor licensed as a wholesale distributor.

(c) Returns or exchanges of prescription drugs that may or may not be salable, including any redistribution by a receiving wholesaler, shall not be subject to the requirements of KRS 315.406 if they are exempt from the pedigree requirements of the federal regulations for the federal Prescription Drug Marketing Act of 1987 as amended by the Prescription Drug Amendments of 1992 and any amendments thereto.

(2) A manufacturer or wholesale distributor shall supply prescription drugs only to a person or entity licensed to possess or distribute prescription drugs to an end user.

(3) Prescription drugs supplied by a manufacturer or wholesale distributor shall be delivered only to the business address of the licensee or the address listed on the license, to the address of a health-care entity authorized by the licensee, or to an authorized person or



agent of the licensee at the premises of the manufacturer or wholesale distributor if the identity and authority of the authorized agent is established.

(4) A licensed wholesale distributor, pharmacy, or other person authorized by law to furnish prescription drugs to an end user shall be accountable for their returns process and shall ensure that all aspects of their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 5, effective July 15, 2008.

**315.406 Prescription drug pedigree for drugs leaving normal distribution channel --  
Administrative regulations.**

(1) (a) As of the date specified by an administrative regulation promulgated by the board pursuant to KRS Chapter 13A, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(b) A retail pharmacy or a pharmacy warehouse shall comply with paragraph (a) of this subsection only if it engages in wholesale distribution of prescription drugs.

(2) The board shall specify the requirements for the contents and maintenance of a pedigree that are consistent with the federal requirements.

(3) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to implement the provisions of this section no later than one hundred eighty (180) days after July 15, 2008.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 6, effective July 15, 2008.

**315.408 Electronic track and trace system.**

(1) The board shall not require the use of an electronic track and trace system to initiate, provide, receive, or maintain a pedigree by a person or entity licensed to possess, distribute, dispense, or administer prescription drugs for use by an end user until the FDA develops and implements standards for identification, validation, authentication, and tracking and tracing of prescription drugs pursuant to 21 U.S.C. sec. 355e. The electronic track and trace system requirements by the board shall meet the FDA's standards for all prescription drugs covered by the FDA standards.

(2) Upon implementation of FDA standards for an electronic track and trace system, the requirements relating to a pedigree in KRS 315.406 shall be superseded by the FDA standards and shall not apply to any prescription drugs specified in the FDA standards.

(3) Prior to promulgation of any administrative regulation under KRS Chapter 13A that requires the use of an electronic track and trace system, the board shall consult with manufacturers, wholesale distributors, and pharmacies regarding implementation of the electronic track and trace system requirements and publish a report on its Web site about implementation issues, including but not limited to universal availability, technical and operational feasibility, and reliability for manufacturers, wholesale distributors, and pharmacies.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 7, effective July 15, 2008.

**315.410 Order to cease distribution of prescription drugs -- Hearing.**

(1) The board shall issue an order to the appropriate person or entity, including but not limited to wholesale distributors or retailers, to immediately cease distribution of prescription drugs within the Commonwealth if there are reasonable grounds to believe:

- (a) 1. The distribution of the prescription drug is in violation of KRS 315.406;
- 2. The prescription drug is accompanied by a falsified pedigree in violation of KRS 315.406; or
- 3. The prescription drug is a counterfeit prescription drug; and
- (b) Other procedures to intercede would result in an unreasonable delay.

(2) A person in receipt of an order to cease distribution shall be notified in writing of the right to an administrative hearing to be conducted in accordance with KRS Chapter 13B no later than ten (10) days, excluding weekends and holidays, after the date of the order. If, after a hearing is conducted, the hearing officer determines that there are inadequate grounds to support the order, the order shall be vacated.

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 8, effective July 15, 2008.

**315.412 Penalties for violation of KRS 315.400 to 315.410.**

(1) A person engaged in the wholesale distribution of prescription drugs who unknowingly violates any provision of KRS 315.400 to 315.410 may be fined not more than five thousand dollars (\$5,000).

(2) A person engaged in the wholesale distribution of prescription drugs who acts with gross negligence and violates any provision of KRS 315.400 to 315.410 may be fined not more than fifteen thousand dollars (\$15,000).

(3) A person engaged in the wholesale distribution of prescription drugs who knowingly violates any provision of KRS 315.400 to 315.410 may be fined not more than one hundred thousand dollars (\$100,000).

**Effective:** July 15, 2008

**History:** Created 2008 Ky. Acts ch. 124, sec. 9, effective July 15, 2008.

**315.500 Emergency authority for pharmacists during state of emergency -- Executive order -- Time limit -- Actions authorized -- Extension.**

(1) When the Governor declares a state of emergency pursuant to KRS 39A.100, the Governor may issue an executive order for a period of up to thirty (30) days giving pharmacists emergency authority. The executive order shall designate the geographical area to which it applies. In the executive order, the Governor may vest pharmacists with the authority to:

- (a) Dispense up to a thirty (30) day emergency supply of medication;
- (b) Administer immunizations to children pursuant to protocols established by the Centers for Disease Control and Prevention, the National Institutes of Health, or the National Advisory Committee on Immunization Practices or determined to be appropriate by the commissioner of public health or his or her designee;
- (c) Operate temporarily, a pharmacy in an area not designated on the pharmacy permit; and

(d) Dispense drugs as needed to prevent or treat the disease or ailment responsible for the emergency pursuant to protocols established by the Centers for Disease Control and Prevention or the National Institutes of Health or determined to be appropriate by the commissioner of public health or his or her designee to respond to the circumstances causing the emergency.

(2) The provisions of this section may be extended, in writing, by the Governor if necessary to protect the lives or welfare of the citizens.

**Effective:** July 15, 2010

**History:** Created 2010 Ky. Acts ch. 22, sec. 1, effective July 15, 2010.

**315.505 Administrative regulations to effectuate authority granted in KRS 315.500(1).**

The Kentucky Board of Pharmacy may promulgate administrative regulations in accordance with KRS Chapter 13A to allow pharmacists to effectuate the authority granted in KRS 315.500(1).

**Effective:** July 15, 2010

**History:** Created 2010 Ky. Acts ch. 22, sec. 2, effective July 15, 2010.

**315.510 Short title.**

KRS 315.510 to 315.524 shall be known and may be cited as the Home Medical Equipment and Services Provider Licensure Act.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 1, effective July 12, 2012.

**315.512 Definitions for KRS 315.510 to 315.524.**

As used in KRS 315.510 to 315.524, unless the context requires otherwise:

(1) "Applicant" means a person who applies for licensure by the board as a home medical equipment and services provider;

(2) "Board" means the Kentucky Board of Pharmacy established in KRS 315.150;

(3) "Home medical equipment" means durable medical equipment which:

(a) Withstands repeated use;

(b) Is primarily and customarily used to serve a medical purpose;

(c) Is generally not useful to a person in the absence of illness or injury; and

(d) Is appropriate for use in the home;

(4) "Providing home medical equipment and services" means the sale, lease, rental, delivery, installation, maintenance, replacement, or instruction in the use of home medical equipment, related equipment and supplies, and mobility enhancing equipment used by a sick or disabled person to allow the person to be maintained in his or her residence and which is funded through a third-party payor;

(5) "Home medical equipment and services provider" or "provider" means a person engaged in the business of providing home medical equipment and services, either directly or through a contractual arrangement, to an unrelated sick or disabled person in the residence of that person; and

(6) "Person" has the same meaning as in KRS 446.010.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 2, effective July 12, 2012.

**315.514 License required to provide or hold oneself out as providing home medical equipment and services -- Exemptions.**

(1) No person shall provide home medical equipment and services, or use the title "home medical equipment and services provider" in connection with his or her profession or business, without a license issued by the board.

(2) Unless home medical equipment and services are provided through a separate legal entity, nothing in KRS 315.510 to 315.524 or any administrative regulations promulgated thereunder shall be construed as preventing or restricting the practices, services, or activities of the following:

- (a) A person licensed or registered in this state under any other law who is engaging in the profession or occupation for which he or she is licensed or registered;
- (b) Health care practitioners who lawfully prescribe or order home medical equipment and services, or who use home medical equipment and services to treat their patients;
- (c) Home health agencies that do not engage in the provision of home medical equipment and services;
- (d) Hospitals that provide home medical equipment and services only as an integral part of patient care;
- (e) Manufacturers and wholesale distributors of home medical equipment who do not sell, lease, or rent home medical equipment directly to a patient;
- (f) Pharmacies that are engaged in the sale, lease, or rental of home medical equipment and services;
- (g) An employee of a person licensed under KRS 315.510 to 315.524;
- (h) Hospice programs that do not involve the sale, lease, or rental of home medical equipment and services;
- (i) Skilled nursing facilities that do not involve the sale, lease, or rental of home medical equipment and services;
- (j) Government agencies, including fire districts which provide emergency medical services; and
- (k) Notwithstanding subsection (1) of this section, an out-of-state provider whose primary business is the manufacture, distribution, or both, of highly specialized equipment who ships that equipment into this state if that equipment is not provided by a licensed Kentucky home medical equipment and services provider.

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 56, sec. 4, effective June 24, 2015. -- Created 2012 Ky. Acts ch. 73, sec. 3, effective July 12, 2012.

**315.516 Legend or order from health care practitioner required.**

A person licensed under KRS 315.510 to 315.524 shall provide home medical equipment and services that carry a legend or require an order from a licensed health care practitioner.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 4, effective July 12, 2012.

**315.518 Application for license -- Fee -- Record retention -- Administrative regulations -- Confidentiality.**

(1) A home medical equipment and services provider shall be licensed by the board under KRS 315.510 to 315.524 prior to engaging in providing home medical equipment and services in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by

administrative regulation not to exceed two hundred dollars (\$200) initially per year or increase more than twenty-five dollars (\$25) per year up to a maximum of four hundred dollars (\$400). Upon receipt of an application for a license to operate as a home medical equipment and services provider, the board shall issue a license if the provider meets the standards and requirements of this chapter and the administrative regulations of the board.

(2) Home medical equipment and services providers shall be required to maintain adequate records of all home medical equipment and services provided as established by administrative regulation by the board. Records shall be made available to agents of the board for inspection at reasonable times. The board may require by administrative regulation that home medical equipment and services providers periodically report to the board all home medical equipment and services provided.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under KRS 315.121.

(4) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure.

(5) Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 5, effective July 12, 2012.

**315.520 Issuance and renewal of licenses -- Separate license required for each location -- Display of license -- Transfer of license prohibited.**

(1) The board shall refuse to renew any license to operate unless the home medical equipment and services provider meets the standards and requirements of KRS 315.510 to 315.524 and the administrative regulations of the board. The board shall act upon an application for a license within thirty (30) days after the receipt thereof.

(2) A separate license shall be required for each location of a home medical equipment and services provider.

(3) A home medical equipment and services provider shall display its license at its place of business.

(4) Each license as a home medical equipment and services provider, unless sooner suspended or revoked, shall expire on September 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by such reasonable renewal fee as may be set by administrative regulation of the board, not to exceed two hundred dollars (\$200) initially per year nor to increase more than twenty-five dollars (\$25) per year up to a maximum of four hundred dollars (\$400). An additional fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by September 30 of each year.

(5) Licenses to operate shall be issued only for the premises and persons named in the application and shall not be transferable.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 6, effective July 12, 2012.

### **315.522 Reciprocity with bordering states.**

- (1) (a) The board may grant a license on the basis of reciprocity to a home medical equipment and services provider located in one (1) of Kentucky's seven (7) contiguous bordering states that licenses home medical equipment and services providers if:
1. The out-of-state provider physically located in one (1) of Kentucky's seven (7) contiguous bordering states possesses a valid license from a jurisdiction that grants the same privileges to persons licensed by the Commonwealth as the Commonwealth grants to persons licensed by the other jurisdiction;
  2. The requirements for licensure in the contiguous bordering state, including but not limited to a requirement for a physical location in the state as a condition of issuing or renewing a license, are substantially similar to the requirements under KRS 315.510 to 315.524; and
  3. The out-of-state provider seeking licensure states that he or she has studied, is familiar with, and shall abide by KRS 315.510 to 315.524 and the administrative regulations promulgated thereunder.
- (b) 1. Notwithstanding subsection (2) of this section, the board may grant a license on the basis of reciprocity to a home medical equipment and services provider physically located in one (1) of Kentucky's seven (7) contiguous bordering states that does not license home medical equipment and services providers if the out-of-state provider seeking to operate in Kentucky states by affidavit that he or she has studied, is familiar with, and shall abide by KRS 315.510 to 315.524 and the administrative regulations promulgated thereunder; and
2. The contiguous bordering state grants the same privileges to persons licensed in the Commonwealth as the Commonwealth grants to providers from the state described in paragraph (b)1. of this subsection.

(2) If the requirements for licensure under KRS 315.510 to 315.524 and the administrative regulations promulgated thereunder are more restrictive than the standards of a contiguous jurisdiction, then the out-of-state provider shall comply with the additional requirements of KRS 315.510 to 315.524 to obtain a reciprocal license.

**Effective:** June 24, 2015

**History:** Amended 2015 Ky. Acts ch. 56, sec. 2, effective June 24, 2015. -- Created 2012 Ky. Acts ch. 73, sec. 7, effective July 12, 2012.

### **315.524 Providing home medical equipment and services without license -- Penalty.**

(1) A person who engages in the business of providing home medical equipment and services and who is required to be licensed under KRS 315.510 to 315.524 and who knowingly provides home medical equipment and services without a license issued under this chapter commits a Class A misdemeanor.

(2) Each day a violation of this section continues constitutes a separate offense.

**Effective:** July 12, 2012

**History:** Created 2012 Ky. Acts ch. 73, sec. 8, effective July 12, 2012.

**315.990 Penalties.**

(1) Except for the provisions of KRS 315.320, any person violating any provision of KRS Chapter 315 shall be fined for each offense not less than one hundred dollars (\$100) nor more than one thousand dollars (\$1,000) or imprisoned in the county jail for not more than six (6) months, or both. Each week that any provision of KRS 315.020, 315.030, or 315.035 is violated shall also constitute a separate offense.

(2) Any person convicted of willfully resisting, preventing, impeding, obstructing, threatening, or interfering with the officers, agents, or inspectors of the board in the administration of the provisions of this chapter shall be guilty of a Class A misdemeanor.

(3) The board may levy an administrative fine not to exceed five thousand dollars (\$5,000) for each offense, for any violation of KRS 315.121. All such fines shall be deposited to the credit of the licensing board to be used by the board in carrying out the provisions of this chapter.

(4) The board may refuse to issue or renew a permit, or may suspend, temporarily suspend, revoke, fine, or reasonably restrict any permit holder for any violation of KRS 315.0351. Any administrative fine levied by the board shall not exceed five thousand dollars (\$5,000) for any violation of KRS 315.0351. All such fines shall be deposited to the credit of the licensing board to be used by the Board of Pharmacy in carrying out the provisions of this chapter.

(5) For a violation of KRS 315.320, the Board of Pharmacy may, in addition to any other civil or criminal penalty, levy an administrative fine not exceeding one hundred thousand dollars (\$100,000). All such fines shall be deposited to the credit of the Board of Pharmacy in carrying out the provisions of this chapter.

**Effective:** June 20, 2005

**History:** Amended 2005 Ky. Acts ch. 150, sec. 21, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 24, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 155, sec. 2, effective July 13, 1990. -- Amended 1982 Ky. Acts ch. 191, sec. 20, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 18. -- Amended 1950 Ky. Acts ch. 16, sec. 1. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 1376t-1, 2619, 2620, 2625, 2628.

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## **TITLE 201 - GENERAL GOVERNMENT CABINET**

### **Chapter 2 Board of Pharmacy**

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<b>201 KAR 2:240</b>	Special limited pharmacy - charitable pharmacy
<b>201 KAR 2:250</b>	Pharmacist Recovery Network Committee
<b>201 KAR 2:260</b>	Automated Pharmacy System in Residential Hospice Facilities
<b>201 KAR 2:270</b>	Expungement
<b>201 KAR 2:280</b>	Prescription dispensing for formulary compliance
<b>201 KAR 2:300</b>	Common database
<b>201 KAR 2:310</b>	Compounding for a practitioner's office or institutional administration
<b>201 KAR 2:320</b>	Permit requirements for manufacturers
<b>201 KAR 2:330</b>	Emergency pharmacy powers
<b>201 KAR 2:340</b>	Special pharmacy permit for clinical practice
<b>201 KAR 2:350</b>	Home Medical Equipment Service Providers
<b>201 KAR 2:360</b>	Naloxone dispensing
<b>201 KAR 2:370</b>	Pharmacy services in long-term care facility [LTCF]

## **201 KAR 2:010. Schools approved by the board.**

RELATES TO: KRS 315.050

STATUTORY AUTHORITY: KRS 315.050, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(1) requires the board to approve the schools or colleges of pharmacy whose curricula or course of studies are acceptable. This administrative regulation establishes the educational standards for an applicant for licensure as a pharmacist in Kentucky and identifies the acceptable and approved colleges or schools of pharmacy from which an applicant shall graduate.

Section 1. An applicant for licensure as a pharmacist, shall have graduated and received a degree in an accredited pharmacy degree program which has been approved by the Board of Pharmacy. A program shall be considered approved if the program's standards are equivalent to the minimum standards for accreditation for a similar program established by:

- (1) The American Council on Pharmaceutical Education in:
  - (a) "Accreditation Manual for Professional Programs"; or
  - (b) "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree"; or
- (2) The Canadian Council for Accreditation of Pharmacy Programs in "Accreditation Standards and Guidelines for Pharmacy Professional Degree Programs in Canada".

Section 2. An applicant for licensure as a pharmacist who shall have graduated and received a degree in a foreign pharmacy degree program, other than from a college or school accredited by the Canadian Council for Accreditation of Pharmacy Programs shall be deemed to be a graduate of a pharmacy degree program which has been approved by the Board of Pharmacy if the applicant has obtained a Foreign Pharmacy Graduate Examination Committee Certificate through the Foreign Pharmacy Graduate Examination Committee Certification Program which is administered by the National Association of Boards of Pharmacy Foundation.

Section 3. Incorporation by Reference.

- (1) The following material is incorporated by reference:
  - (a) "Accreditation Manual for Professional Programs", 8th Edition (3rd Printing) January 1995, American Council on Pharmaceutical Education;
  - (b) "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree," June 14, 1997, American Council on Pharmaceutical Education; and
  - (c) "Accreditation Standards and Guidelines for Pharmacy Professional Degree Programs in Canada", Revised January 1998, Canadian Council for Accreditation of Pharmacy Programs.
- (2) This material may be inspected, copied, or obtained at the Kentucky Board of Pharmacy, 1024 Capital Center Drive, Suite 210, Frankfort, Kentucky 40601-8204, Monday through Friday 8 a.m. to 4:30 p.m. \*

(4 Ky.R. 218; eff. 1-4-78; Am. 11 Ky.R. 1612; eff. 6-4-85; 12 Ky.R. 498; eff. 12-10-85; 16 Ky.R. 791; eff. 1-12-90; 18 Ky.R. 1911; eff. 2-19-92; 19 Ky.R. 443; eff. 10-8-92; 25 Ky.R. 2925; 26 Ky.R. 718; eff. 10-20-99.)

\* PLEASE NOTE: The Board's address has changed since this regulation went into effect. The current address for the Board is The Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601.

**201 KAR 2:015. Continuing education.**

RELATES TO: KRS 315.065, 315.120

STATUTORY AUTHORITY: KRS 315.065, 315.110(1), 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.065(2) and (3) requires the Board of Pharmacy to establish continuing education requirements for pharmacists. This administrative regulation establishes requirements for the continuing pharmacy education of registered pharmacists and requires all registered pharmacists holding a license issued by the board to participate in continuing pharmacy education as a means of renewal of their licenses.

**Section 1. Definitions.**

- (1) "Continuing education unit" or "CEU" is defined by KRS 315.010(7).
- (2) "Sponsor" means a person, school, association, company, corporation, or group who wishes to develop a continuing education program.

**Section 2. Continuing education hours for credit may be compiled in the following areas if the sponsor grants the participant a certificate of completion:**

- (1) Cassette and audiovisual presentation;
- (2) In-company professional seminars;
- (3) Accredited school of pharmacy continuing education programs;
- (4) Postgraduate courses in pharmaceutical sciences;
- (5) Correspondence courses;
- (6) Programs granted continuing education credit by other states;
- (7) The Accreditation Council for Pharmacy Education;
- (8) Continuing education television series;
- (9) Programs sponsored by allied professional groups; or
- (10) Professional society and association sponsored programs.

**Section 3. Continuing education sponsors shall submit to the board for final accreditation continuing education programs for participants.**

- (1) Programs shall be submitted to the board at least sixty (60) days prior to planned participation so the participants can know the value of the experience prior to actual participation.
- (2) Program changes shall be submitted to and accredited by the board, or the evaluation and accreditation of the program shall be void.
- (3) Continuing education credit shall be given only once for each program per participant.
- (4) Sponsors shall retain a file of each participant's program completion for three (3) years.
- (5) The board approval of each program shall expire at the end of three (3) years.

**Section 4. (1) Sponsors and pharmacists requesting approval of continuing pharmacy education shall submit the Kentucky Board of Pharmacy Continuing Education Program Approval Form. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs completed for three (3) years and submit the certification to the board on request.**

(2) Submission of a fraudulent statement or certificate concerning continuing pharmacy education shall subject the pharmacist to discipline as provided in KRS 315.121.

Section 5. (1) A pharmacist shall:

- (a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31; and
  - (b) Not transfer or apply excess hours or units for future years.
- (2) A pharmacist may be granted a deferral on a year-to-year basis at the discretion of the board for illness, incapacity, or other extenuating circumstances.
- (3) A pharmacist first licensed by the board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions for that year.

Section 6. All pharmacists shall keep the board informed of their correct addresses.

Section 7. CEU may be transferred from another state to Kentucky if the transfer state recognizes Kentucky CEU.

Section 8. A licensee who failed to timely renew his or her license shall:

- (1) Comply with the applicable provisions of KRS 315.120(2) or (3); and
- (2) Complete fifteen (15) hours of continuing education for each year the applicant failed to renew his or her license, up to a maximum of seventy-five (75) hours.

Section 9. Incorporation by Reference.

- (1) The "Kentucky Board of Pharmacy Continuing Education Program Approval Form", 2002, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(4 Ky.R. 218; eff. 1-4-78; Am. 11 Ky.R. 1612; eff. 6-4-85; 16 Ky.R. 791; eff. 1-12-90; 28 Ky.R. 1906; 2192; eff. 3-28-2002; 37 Ky.R. 2041; 2376; eff. 5-6-2011; 41 Ky.R. 2609; 42 Ky.R. 272; eff. 9-4-2015.)

## **201 KAR 2:020. Examination.**

RELATES TO: KRS 218A.205(3)(g), 315.050

STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.050(2), 315.191(1), (2), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(2) and 315.191(1)(c) authorize the board to promulgate administrative regulations to prescribe the time, place, method, manner, scope, and subjects of examinations. KRS 218A.205(3)(g) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes the examination and application requirements for obtaining a license to practice pharmacy in Kentucky.

Section 1. The examination for licensure shall include:

- (1) The North American Pharmacist Licensure Examination (NAPLEX); and
- (2) The Multistate Pharmacy Jurisprudence Examination (MPJE).

Section 2. The passing score on the required examinations shall be:

- (1) At least seventy-five (75) on the basis of the NAPLEX and the MPJE grades shall not be used in computing the NAPLEX; and
- (2) At least seventy-five (75) on the basis of the MPJE.

Section 3. If an applicant fails to obtain the necessary scores in any of the tests described in Section 2 of this administrative regulation, the applicant may upon proper application retake the tests upon the payment of the fee set forth in 201 KAR 2:050 plus any direct costs for test materials and supplies. An applicant who has failed any test may retake that test within one (1) year of the date the applicant first failed the test without having to reapply.

Section 4. All results of examinations shall be preserved according to the Board of Pharmacy Record Retention Schedule.

Section 5. Fees submitted with an application shall be nonrefundable.

Section 6. Prior to approval for examination, an applicant shall:

- (1) Submit to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police or the Federal Bureau of Investigation; and
- (2) Submit to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 7. License, Fee. An applicant shall submit:

- (1) An Initial Application for Pharmacist Licensure pursuant to KRS 315.050; and
- (2) As appropriate, the fee established by 201 KAR 2:050, Section 1(1).

Section 8. Incorporation by Reference.

- (1) "Initial Application for Pharmacist Licensure", Form 1, 7/2012, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday 8:00 a.m. to 4:30p.m.

(1 Ky.R. 9; eff. 9-11-74; Am. 7 Ky.R. 403; eff. 12-3-80; 9 Ky.R. 11; eff. 8-11-82; 11 Ky.R. 1614; eff. 6-4-85; 16 Ky.R. 793; eff. 1-12-90; 19 Ky.R. 443; eff. 10-8-92; 26 Ky.R. 866; 1117; eff. 12-15-99; 32 Ky.R. 1462; 1879; eff. 5-5-2006; 39 Ky.R. 501; eff. 2-1-2013; 39 Ky.R. 2377; eff. 8-21-2013.)

### **201 KAR 2:030. License Transfer.**

RELATES TO: KRS 315.191(1)(c), (d), 315.210

STATUTORY AUTHORITY: KRS 218A.205(7), 315.191(1)(a), (c), (d), 315.210

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 authorizes the board to establish conditions for licensure by reciprocity. KRS 218A.205(7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity.

Section 1. Definitions. (1) "Board" is defined by KRS 315.010(3).

- (2) "License transfer" means a license to practice pharmacy in Kentucky issued by the board to a pharmacist licensed in another jurisdiction.
- (3) "NABP" means the National Association of Boards of Pharmacy.

Section 2. An applicant licensed in another jurisdiction shall be eligible for license transfer, if the:

- (1) Requirements for licensure of the jurisdiction that granted his or her license met or exceeded Kentucky requirements for licensure when the license in the other jurisdiction was granted;
- (2) Applicant holds in good standing, an active license to practice pharmacy;
- (3) Applicant has:
  - (a) Completed and certified the NABP Preliminary Application for Transfer of Pharmacist License form; and
  - (b) Received an NABP Official Application for Transfer of Pharmacist License;
- (4) Applicant is currently in good standing in the jurisdiction from which he or she has applied;
- (5) Applicant has successfully completed an examination in jurisprudence;
- (6) Applicant has submitted to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and
- (7) Applicant has submitted to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 3. Required Information. An applicant shall provide the information required by the NABP Preliminary Application for Transfer of Pharmacist License form, including:

- (1) Name, maiden, and other names used currently or previously;
- (2) Address, telephone number;
- (3) Date and place of birth, and current age;
- (4) Social Security number;
- (5) Citizenship;
- (6) Gender;
- (7) State of original license by examination, including:
  - (a) License number;
  - (b) Original date of issue;
  - (c) Current status of original licensure; and
  - (d) State for which license transfer is requested;
- (8) Pharmacy education, including:
  - (a) Name and location of pharmacy school;
  - (b) Name of pharmacy degree;
  - (c) Date degree was received; and
  - (d) Other professional degrees, including the information specified by paragraphs (a) to (c) of this subsection;
- (9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate Examination Committee, and, if so, the examination equivalency number assigned;
- (10) Total hours of practical experience prior to licensure as a pharmacist, including the State Board of Pharmacy with which the hours are filed;
- (11) States, dates, and results of pharmacist licensure examinations;
- (12) Pharmacist licenses obtained by:
  - (a) Score transfer; and
  - (b) Licensure transfer;

- (13) Practice and employment, including nonpharmacist employment, from initial licensure to the date of filing the application; and
- (14) Record of charges, convictions, and fines imposed, or certification that the applicant has not been convicted, fined, or disciplined, or had a license revoked.

Section 4. The board shall accept a license transfer from a jurisdiction that:

- (1) Is an active member of the NABP; and
- (2) Grants license transfer to a pharmacist pursuant to conditions and requirements that are the equivalent of conditions and requirements established by the board.

Section 5. An applicant shall take and pass the Multistate Pharmacy Jurisprudence Examination administered by the NABP.

Section 6. Fee. An applicant shall include the fee specified by 201 KAR 2:050, Section 1(2), (20).

Section 7. (1) "NABP Preliminary Application for Transfer of Pharmacist License", 3/06, is incorporated by reference.

- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(Rx-3, 11; 1 Ky.R. 147; eff. 12-11-74; Am. 16 Ky.R. 794; 1943; eff. 3-8-90; 24 Ky.R. 1115; 1865; eff. 3-16-98; 25 Ky.R. 2185; 2832; eff. 6-16-99; 26 Ky.R. 1436; 1798; eff. 4-12-2000; 32 Ky.R. 1463; 1879; eff. 5-5-06; 39 Ky.R. 502; 1371; eff. 2-1-2013; 39 Ky.R. 2378; eff. 8-21-2013; 41 Ky.R. 298; 738; eff. 10-15-2014.)

#### **201 KAR 2:040. Registration of pharmacist interns.**

RELATES TO: KRS 315.010(16), 315.020(3), (4), 315.050(4), (5), 315.191(1)(h)

STATUTORY AUTHORITY: KRS 315.050(4), (5), 315.191(1)(a), (h)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is required by KRS 315.050(4) to establish standards for pharmacy intern certification. KRS 315.191(1)(h) authorizes the board to establish an internship program for training, qualifications, and registration of applicants for registration of pharmacist interns. This administrative regulation establishes the standards for training, qualifications, and registration of pharmacist interns.

Section 1. Definitions. (1) "Academic experience program" means a course or series of courses taken by a pharmacist intern at a school or college of pharmacy approved by the board that involves actual practice of pharmacy experiences.

- (2) "Preceptor" means the pharmacist who is responsible to the board for the practice of pharmacy experiences of a pharmacist intern.

Section 2. An applicant for registration as a pharmacist intern shall:

- (1) File an Application for Registration as a Pharmacist Intern, Form I, with the board;
- (2) Attach a recent head and shoulders passport photograph, that is not a proof copy or plastic identification; and
- (3) Submit proof of acceptance by a college or school of pharmacy approved by the board.

Section 3. An applicant for examination for licensure as a pharmacist shall:

- (1) Complete 1,500 hours of internship;
- (2) Be awarded credit for internship for hours worked in a pharmacy or in related research during the time the pharmacist intern is enrolled in an approved school or college of pharmacy;
- (3) Not be awarded credit for hours worked in a pharmacy or in related research during the period the pharmacist intern is completing the academic experience program;
- (4) Be limited to internship credit:
  - (a) Of forty-eight (48) hours per week during non-academic sessions if the pharmacist intern is in good standing with a college or school of pharmacy and the board; and
  - (b) Of twenty (20) hours per week during academic sessions in a college or school of pharmacy. The maximum credit allowed for this enrolled time shall be 500 hours;
- (5) Be given credit for the following forms of internship:
  - (a) Completion of an academic experience program;
  - (b) Work performed in a pharmacy under the supervision of a preceptor;
  - (c) Work or research related to the practice of pharmacy that was performed under the supervision of a preceptor for a government body, college or university, pharmacy business, or other entity if the pharmacist intern has received prior approval by the board. The maximum credit allowed for this time shall be 400 hours and the pharmacist intern shall also file an essay of at least 500 words describing the work or research experience and the relation of the work or research to the practice of pharmacy, which shall be approved by the board president; or
  - (d) An internship performed outside of Kentucky if the:
    1. Requirements for internship in that state are at least equivalent to the requirements established in this administrative regulation; and
    2. Board of licensure in that state has certified that the preceptor, pharmacy, government body, college or university, pharmaceutical business, or other entity is in good standing; and
- (6) Not be awarded credit for an internship completed prior to registration with the board.

Section 4. A pharmacist intern shall: (1) Be issued a Registration Identification Card;

- (2) Carry the Registration Identification Card when on duty;
- (3) Show it upon request to a member of the board or its authorized agent; and
- (4) Notify the board within thirty (30) days of any charge of:
  - (a) A felony;
  - (b) A violation of drug laws; or
  - (c) A violation of alcohol laws.

Section 5. The registration of a pharmacist intern shall be revoked if the pharmacist intern is not:

- (1) Currently enrolled in a college or school of pharmacy approved by the board;
- (2) A current applicant for licensure as a pharmacist in Kentucky; or
- (3) Awaiting the results of an examination.



Section 6. The registration of a pharmacist intern shall not be revoked when the intern is not currently enrolled in a college or school of pharmacy approved by the board if the board finds that:

- (1) The intern is on a semester break; or
- (2) Personal or family health concerns or other reasons beyond the control of the pharmacist intern necessitate a temporary absence from enrollment and the absence is approved by the board.

Section 7. A person who is not registered as a pharmacist intern shall not:

- (1) Hold himself or herself out as a pharmacist intern; or
- (2) Perform the duties of a pharmacist intern.

Section 8. (1) A preceptor shall be a pharmacist who:

- (a) Has a license in good standing;
  - (b) Has been licensed by the board for at least one (1) year; and
  - (c) Has requested in writing to be designated as a preceptor.
- (2) A preceptor shall be actively engaged in the practice of pharmacy in the location where the pharmacist intern performs his or her internship.
- (3) The preceptor shall supervise only one (1) pharmacist intern at a time for the purpose of the intern obtaining credit for the practice of pharmacy experience, unless the pharmacist is supervising interns as a faculty member at a school or college pharmacy approved by the board during an academic experience program.

Section 9. Credit for Non-Academic Experience Programs. (1) Within ten (10) days of beginning an internship credit for non-academic experience program, a pharmacist intern shall submit a Pharmacist Preceptor's Affidavit, Form II.

- (2) On or before graduation from a college or school of pharmacy, a pharmacist intern shall submit an Internship Report, Form III.

Section 10. Credit for Academic Experience Programs. (1) For a Doctor of Pharmacy degree, credit shall be awarded for each hour of successful completion of an academic experience program at a college or school of pharmacy approved by the board.

- (2) An academic experience program shall be reported on an Academic Experience Affidavit, Form IV, which shall be filed with the board upon completion of the academic experience program or prior to certification for examination.

Section 11. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Application for Registration as a Pharmacist Intern", Form I, 11/2012;
  - (b) "Pharmacist Preceptor's Affidavit", Form II, 11/2012
  - (c) "Internship Report", Form III, 11/2012; and
  - (d) "Academic Experience Affidavit", Form IV, 11/2012.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601 Monday through Friday, 8 a.m. to 4:30 p.m.

(Rx-6; 1 Ky.R. 9; eff. 9-11-74; Am. 9 Ky.R. 247; eff. 9-8-82; 11 Ky.R. 1125; eff. 3-12-85; 16 Ky.R. 795; eff. 1-12-90; 25 Ky.R. 2187; 2832; eff. 6-16-99; 26 Ky.R. 1023; 1404; eff. 1-12-2000; 34 Ky.R. 1095; 1703; eff. 2-1-2008; 39 Ky.R. 1051; 1372; eff. 2-1-2013; 41 Ky.R. 300; 739; eff. 10-15-2014.)

## **201 KAR 2:045. Technicians.**

RELATES TO: KRS 315.010(18), (25), 315.020(4)(b), 315.191(1)(a), (g), (l)

STATUTORY AUTHORITY: KRS 315.010(18), (25), 315.020(4)(b), 315.191(1)(a), (g), (l)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations governing pharmacy technicians. KRS 315.010(18) authorizes the board to permit a pharmacy technician to work under the general supervision of a pharmacist. KRS 315.191(1)(l) authorizes the board to promulgate administrative regulations establishing the qualifications a pharmacy technician is required to obtain prior to practicing under the general supervision of a pharmacist. This administrative regulation establishes the qualifications required for a pharmacy technician to practice under the general supervision of a pharmacist, and establishes the scope of practice for a pharmacy technician.

Section 1. A person shall be recognized by the board as a certified pharmacy technician, if:

- (1) (a) He has successfully completed the National Certification Examination administered by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians (ICPT); and  
(b) The certificate issued by the Pharmacy Technician Certification Board or the ICPT is current; or
- (2) He has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee.

Section 2. A certified pharmacy technician, subject to the supervision, as defined by KRS 315.010(25), of a pharmacist may perform the following functions:

- (1) Certify for delivery unit dose mobile transport systems that have been refilled by another technician;
- (2) Within a nuclear pharmacy, receive diagnostic orders; and
- (3) (a) Initiate or receive a telephonic communication from a practitioner or practitioner's agent concerning refill authorization, after he clearly identifies himself as a certified pharmacy technician;  
(b) If a practitioner or practitioner's agent communicates information that does not relate to the refill authorization:
  1. A technician shall immediately inform the pharmacist; and
  2. The pharmacist shall receive the communication.

Section 3.

- (1) A technician who has not been certified by the Pharmacy Technician Certification Board or the ICPT may perform the functions specified by Section 2 of this administrative regulation under the immediate supervision of a pharmacist.
- (2) A function performed by a certified pharmacy technician or pharmacy technician shall be performed subject to the review of the pharmacist who directed the technician to perform the function.
- (3) A pharmacist who directs a certified pharmacy technician or pharmacy technician to perform a function shall be responsible for the technician and the performance of the function.

(23 Ky.R. 3124; Am. 3806; 4108; eff. 6-16-97; 26 Ky.R. 1687; 2238; eff. 6-12-2000; 35 Ky.R. 2484; 36 Ky.R. 321; eff. 8-12-2009.)

**201 KAR 2:050. Licenses and permits; fees.**

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.402, 315.518(1), 315.520(4)

STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.191(1), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.402(1), 315.518(1), 315.520(4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation provides reasonable fees for this agency to perform all the functions for which it is responsible.

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates and the issuance and renewal of licenses and permits:

- (1) Application for a licensee for pharmacist examination - \$150;
- (2) Application and initial license for a pharmacist license by license transfer - \$250;
- (3) Certifying the grades of a licentiate of Kentucky to the licensing agency of another state - ten (10) dollars;
- (4) Annual renewal of a pharmacist license - seventy (70) dollars;
- (5) Delinquent renewal penalty for a pharmacist license - seventy (70) dollars;
- (6) Annual renewal of an inactive pharmacist license - ten (10) dollars;
- (7) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;
- (8) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;
- (9) Application for a permit to operate a pharmacy - \$100;
- (10) Renewal of a permit to operate a pharmacy - \$100;
- (11) Delinquent renewal penalty for a permit to operate a pharmacy - seventy-five (75) dollars;
- (12) Change of location or change of ownership of a pharmacy or manufacturer permit - seventy-five (75) dollars;
- (13) Application for a permit to operate as a manufacturer - \$100;
- (14) Renewal of a permit to operate as a manufacturer - \$100;
- (15) Delinquent renewal penalty for a permit to operate as a manufacturer - \$100;
- (16) Change of location or change of ownership of a wholesale distributor license - seventy-five (75) dollars;
- (17) Application for a license to operate as a wholesale distributor - \$100;
- (18) Renewal of a license to operate as a wholesale distributor - \$100;
- (19) Delinquent renewal penalty for a license to operate as a wholesale distributor - \$100;
- (20) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services – twenty-five (25) dollars;
- (21) Application for a license to operate as a home medical equipment supplier - \$200;
- (22) Renewal for a license to operate as a home medical equipment supplier - \$200; and
- (23) Delinquent renewal penalty for a license to operate as a home medical equipment supplier - \$150.

(Rx-1; 1 Ky.R. 10; eff. 9-11-74; Am. 4 Ky.R. 122; eff. 11-2-77; 8 Ky.R. 254; eff. 10-7-81; 9 Ky.R. 12; eff. 8-11-82; 1027; eff. 4-6-83; 19 Ky.R. 444; eff. 11-9-92; 25 Ky.R. 2188; 2834; eff. 6-16-99; 32 Ky.R. 1465; 1890; eff. 5-5-2006; 35 Ky.R. 1833; eff. 6-5-09; 39 Ky.R. 504; eff. 2-1-2013.)

**201 KAR 2:061. Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.**

RELATES TO: KRS 218A.205, 315.131, 315.191(4)

STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to the practice of pharmacy, including a process for complaints and hearings. KRS 218A.205(3)(e), (f), and (5) require the board to promulgate administrative regulations relating to complaints, licensure standards, and disciplinary actions. This administrative regulation establishes board procedure for investigations, the administrative hearings process, and the penalties for violations.

Section 1. (1) A complaint against a licensee may:

- (a) Be submitted orally or in writing; and
  - (b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.
- (2) A complaint shall be accepted anonymously if the complaint is accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint is meritorious.
- (3) A complaint shall not be required to be sworn to or notarized.

Section 2. (1) Except as provided by subsection (2) of this section, upon receipt of a complaint, the board shall instruct its staff to:

- (a) Conduct an investigation; and
  - (b) Report the conclusions and recommendations of the investigation to the:
    - 1. Executive director; and
    - 2. Board member assigned by the board to review conclusions and recommendations relating to an investigation.
- (2) If the complaint pertains to the improper, inappropriate, or illegal dispensing of controlled substances, the board shall:
- (a) File a report with the Attorney General's office, the Office of Inspector General's office, and the Department of the Kentucky State Police within three (3) business days;
  - (b) Commence an investigation within seven (7) days of the complaint; and
  - (c) Produce a charging decision within 120 days of the complaint, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.

Section 3. (1) A panel consisting of the assigned board member, the executive director, and the pharmacy drug inspector shall review the conclusions and recommendation relating to an investigation.

- (2) The panel shall recommend one (1) of the following options to the board:
- (a) A reprimand restricting the licensee, permit or certificate holder;
  - (b) The issuance of a formal complaint, order, and notice of hearing;
  - (c) Dismissal of the case with or without prejudice; or
  - (d) Returning the case to the inspector for further investigation.

(3) Documentation of a board reprimand shall be maintained in the appropriate board files.

Section 4. (1) With the approval of the board, the executive director shall notify the licensee, permittee, or certificate holder, in writing, that he or she may request an administrative conference before the executive director and the pharmacy drug inspector to be held prior to the hearing.

(2) The licensee, permit or certificate holder shall be notified that he or she may appear with counsel.

(3) An administrative conference shall be held to determine whether an agreement may be reached to resolve the complaint that is acceptable to all parties.

(4) If an agreement is reached, it shall be submitted to the board for approval and board order.

Section 5. (1) A settlement conference may be requested by the licensee, permit or certificate holder, or the attorney for that person.

(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the board's attorney, the licensee, permit or certificate holder, and the attorney for that person.

(3) If the parties to a settlement conference agree on stipulations, proposed terms, and conditions for an agreed order to resolve the complaint, they shall forward the agreed order to the board for approval.

(4) If the proposed agreed order is approved by the board, the complaint shall be considered resolved and a hearing shall not be held.

Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS 315.131(1).

Section 7. Posthearing Proceedings.

(1) The board shall deliberate on all cases in closed session.

(2) Board counsel shall not attend, or be involved in any manner with, the closed session.

(3) The specific findings of the board shall be made in open session following the board's deliberation.

Section 8. Penalties. (1) Pursuant to KRS 218A.205(3)(e)1., a licensee convicted of a felony offense related to dispensing a controlled substance shall, at a minimum, be permanently banned from dispensing any controlled substance.

(2) Pursuant to KRS 218A.205(3)(e)2., the board shall impose restrictions short of a permanent ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense relating to the dispensing of a controlled substance.

(3) Pursuant to KRS 218A.205(3)(e)3., a licensee disciplined by the licensing board of another state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall, at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action imposed by the licensing board of the other state.

(4) Pursuant to KRS 218A.205(3)(f), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent.

(18 Ky.R. 2449; Am. 2773; eff. 3-4-92; 39 Ky.R. 506; 1374; eff. 2-1-2013.)

**201 KAR 2:070. Prescription intermediary services restricted.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.020(2), 315.121(1), 315.191(2),(8)

NECESSITY, FUNCTION, AND CONFORMITY: By the authority of KRS 315.191(2) the Board of Pharmacy is responsible to control all matters relating to pharmacies and pharmacists with respect to drugs sold by prescriptions only. This administrative regulation assures the public that a registered pharmacist is present and that prescription drugs distribution is curtailed.

Section 1. No pharmacist shall fill and dispense prescriptions obtained from an establishment or place which offers to the public, in any manner, its services as a "pickup station" or "intermediary" for the purpose of having prescriptions filled or delivered unless such establishment or place has a registered pharmacist in full charge of such services.

(Rx-7; 1 Ky.R. 10; eff. 9-11-74.)

**201 KAR 2:074. Pharmacy services in hospitals or other organized health care facilities.**

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: 315.002, 315.005, KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to insure the safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in hospitals or other organized health care facilities.

Section 1. Definitions.

- (1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information and shall be either:
  - (a) A decentralized automated pharmacy system that is located outside the pharmacy department, but within the same institution, and under the supervision of a pharmacist; or
  - (b) A centralized automated pharmacy system from which medications are prepared for final distribution that require the approval of a pharmacist.
- (2) "Institutional pharmacy" means that portion of an acute care hospital licensed pursuant to 902 KAR 20:016 or a pharmacy serving an other organized health care facility engaged in the manufacture, production, sale, or distribution of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, or disease.
- (3) "Investigational drug" means a drug that has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.
- (4) "Other organized health care facility" means a facility:

- (a) With a primary purpose to provide medical care and treatment to inpatients; and
  - (b) That is:
    - 1. An intermediate care facility;
    - 2. A skilled nursing facility;
    - 3. A hospital other than an acute care hospital licensed pursuant to 902 KAR 20:016;
    - 4. A licensed personal care home;
    - 5. A licensed family care home;
    - 6. A nursing home;
    - 7. A nursing facility;
    - 8. An intermediate care facility for mental retardation; or
    - 9. An Alzheimer's nursing home.
- (5) "Unit dose distribution" means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as the doses are needed.

## Section 2. Pharmacy Administration.

### (1) General.

- (a) The pharmacy, organized as a separate department or service, shall be directed by a pharmacist, who shall be thoroughly knowledgeable about institutional pharmacy practice and management.
- (b) The director of pharmacy services shall be responsible for departmental management and the development and implementation of goals and objectives to meet the needs of the institution and shall be responsible to the chief executive officer of the institution or the chief executive officer's designee.
- (c) If the director of pharmacy services is not employed full time, the institution shall establish an ongoing arrangement in writing with a pharmacist to provide services required by this administrative regulation and KRS 315.020(1).
- (d) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director of pharmacy services.

### (2) Pharmacy personnel.

- (a) The institutional pharmacy shall maintain additional pharmacists in cooperation with the institution's administration, either full time or part time, as required to operate safely and effectively to meet the needs of the patients.
- (b) If nonpharmacist personnel are employed, nonpharmacist personnel shall perform all duties under the supervision of a pharmacist and shall not be assigned and shall not perform duties that are to be performed only by a pharmacist.

### (3) Responsibilities.

- (a)
  - 1. Lines of authority and areas of responsibility within the pharmacy shall be clearly defined.
  - 2. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.
- (b)
  - 1. There shall be policies and procedures to provide for selection of drugs as well as a distribution system to serve the needs of the patient.

2. Provision for procurement of drugs in an emergency situation shall be provided for.
- (4) Supportive personnel.
  - (a) Sufficient supportive personnel (technical, clerical, and other) shall be available in order to optimize the participation of pharmacists in activities requiring professional judgment.
  - (b) The training and supervision of supportive personnel shall be the responsibility of the pharmacist.
- (5) Availability.
  - (a) The services of a pharmacist shall be available continuously. If around-the-clock operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call basis, and an adequate night drug cabinet shall be established. The pharmacy itself shall not be designated as the night drug cabinet.
  - (b) A hospital not having a full-time pharmacist, but in which drugs are prepackaged or relabeled or transferred from one (1) container to another, shall obtain a pharmacy permit and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

### Section 3. Physical Facility.

- (1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation, and distribution, patient education and consultation, drug information services, and proper management of the department.
- (2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by authorized pharmacy personnel only.
- (3) (a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:
  1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and
  2. Does not currently possess a pharmacy permit.(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section shall permit access by authorized personnel only.
- (4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.
- (5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:
  - (a) Drug identification;
  - (b) Toxicology;
  - (c) Drug interactions;
  - (d) Parenteral drug compatibility; and
  - (e) Microbiology.

### Section 4. Drug Distribution and Control.

- (1) General. The institutional pharmacy shall be responsible for the procurement, distribution, and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by



the pharmacist with input from other involved hospital or other organized health care facility staff (for example, nurses) and committees (for example, pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed medical practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order within a reasonable amount of time.

(4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.

(5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in an emergency situation.

(6) Labeling and packaging.

(a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.

(b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.

(7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.

(8) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.

(9) Administration.

(a) Drugs shall be administered only upon order of a licensed medical practitioner.

(b) The institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medications. Specific procedures shall be developed in cooperation with appropriate hospital or other health care facility personnel and shall include personnel authorized to schedule, prepare, and administer medications.

(10)(a) Unused medication. The institutional pharmacy shall establish policies and procedures for the disposition of patients' unused medications.

(b) Medication in unit dose form may be reissued if package integrity has been maintained and the product has not expired.

(11) Hospital floor stocks.

(a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.

(b) A pharmacist shall review all orders distributed through floor stock within a reasonable amount of time.

(c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (for example, emergency room, surgery, critical care, or medical or surgical wards).

- (d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly, and documentation shall be maintained to ensure that:
  - 1. Unusable items shall not be present; and
  - 2. All stock items shall be properly labeled and stored.
- (e) This subsection shall not apply to other organized health care facilities.
- (12) Drug recall. There shall be a system for removing from use a drug that has been recalled.
- (13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.
- (14) Emergency drugs.
  - (a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.
  - (b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.
  - (c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.
- (15) Investigational drugs.
  - (a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.
  - (b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date), and providing information about investigational drugs (including proper disposal).
- (16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

#### Section 5. Assuring Rational Drug Therapy.

- (1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.
- (2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.
- (3) The pharmacist shall provide a means to ensure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.

#### Section 6. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for:

- (1) An initial validation of system accuracy prior to use for distribution to patients;
- (2) Ensuring the system:
  - (a) Is properly maintained;
  - (b) Is in good working order;

- (c) Accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and
  - (d) Complies with the recordkeeping, access, and security safeguards pursuant to all applicable state and federal laws;
- (3) Assuring medications are reviewed prior to loading into an automated pharmacy system and distribution;
- (4) Implementing an ongoing quality assurance program that monitors performance of the pharmacy compounding robotics, which is evidenced by written policies and procedures and requires a continued documented validation of doses distributed on a routine basis and annual review of the quality assurance program;
- (5) Establishing policies and procedures if there is a system failure of an automated pharmacy system;
- (6) Providing the board with prior written notice of installation or removal of an automated pharmacy system. This notification shall include the:
  - (a) Name and address of the pharmacy; and
  - (b) Initial location of the automated pharmacy system;
- (7) Oversight for assigning, discontinuing, or changing personnel access to the system, including establishment of written policies and procedures for security and control;
- (8) Reviewing personnel access on at least an annual basis;
- (9) Assuring that the decentralized automated pharmacy system stock is checked at least monthly in accordance with established policies and procedures, including checking for:
  - (a) Accuracy;
  - (b) Integrity of packaging; and
  - (c) Expiration dates;
- (10) Maintaining in the pharmacy the following documentation relating to an automated pharmacy system:
  - (a) The name and address of the pharmacy or inpatient health care facility where the system is being used;
  - (b) The automated pharmacy system manufacturer's name, model, serial number, and software version;
  - (c) A description of how the system is used;
  - (d) Written quality assurance procedures and accompanying documentation of use to determine continued appropriate use of the system as established in subsections (7) and (8) of this section; and
  - (e) Written policies and procedures for system operation, safety, security, accuracy, emergency medication access, access, and malfunction which includes clearly defined down time and procedures; and
- (11) Maintaining adequate security systems and procedures, evidenced by written policies and procedures to:
  - (a) Prevent unauthorized access;
  - (b) Maintain patient confidentiality;
  - (c) Allow user access modification; and
  - (d) Comply with federal and state laws.

## Section 7. Standards.

- (1) (a) All events involving the contents of the automated pharmacy system shall be recorded electronically.  
(b) Records shall be maintained by the pharmacy and be available to the board and shall include the following:
  1. The date, time, and location of the system accessed;
  2. Identification of the individual accessing the system;
  3. Type of transaction;
  4. Name, strength, dosage form, and quantity of drug accessed; and
  5. Name of the patient for whom the drug was ordered, if applicable.
- (2) All medications to be stocked into the centralized automated pharmacy system shall have been previously validated for bar code accuracy by a pharmacist, pharmacist intern, or certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.
- (3) The stocking of medications in a decentralized automated pharmacy system utilizing bar code technology shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician.
- (4) The stocking of medications in a decentralized automated pharmacy system without bar code technology shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.
- (5) If a hospital licensed pursuant to 902 KAR 20:016 utilizes technology that validates appropriate drug, dose, dosage form, route of administration, time of administration, and patient at the exact time of medication administration, the stocking of the decentralized automated pharmacy system shall be done by a pharmacist, pharmacist intern, or certified pharmacy technician.
- (6) A record of medications stocked in an automated pharmacy system shall be maintained for at least five (5) years and shall include:
  - (a) The name of the person repacking the medications; and
  - (b) Documentation of the pharmacist checking the medications.
- (7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.
- (8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.
- (9) All medications initially received in the pharmacy for use in an automated pharmacy system shall be quarantined until validation of bar code accuracy and existence of the item in the database powering automated pharmacy system by a certified pharmacy technician, pharmacist intern, or pharmacist.
- (10) If a medication needs to be repackaged:
  - (a) A pharmacist, pharmacist intern, or certified pharmacy technician shall:
    1. Perform the repackaging and validate the presence of an accurate bar code on the unit dose packaging; and
    2. Document the repackaging process including:
      - a. Manufacturer;
      - b. Date and time of repackaging;
      - c. The person repackaging;
      - d. The lot number or batch number;

- e. The expiration date; and
- f. The quantity repackaged; and
- (b) A pharmacist shall:
  1. Validate for accuracy and integrity prior to the addition to the automated pharmacy system; and
  2. Document the validation including:
    - a. The date and time of the validation;
    - b. The name of the pharmacist validating;
    - c. The lot number or batch number;
    - d. The expiration date; and
    - e. The quantity validated.

(11) A medication returned to the pharmacy from a patient care area shall follow the processes established pursuant to Section 4(10) of this administrative regulation.

(12) A medication distributed by the centralized automated pharmacy system shall be distributed in the delivery device utilized by that system.

(13) A medication distributed by an automated pharmacy system shall be accessed and administered by a professional licensed to administer medications.

(16 Ky.R. 1713; Am. 2150; 17 Ky.R. 2175; eff. 12-13-90; 30 Ky.R. 75; 577; eff. 8-20-2003; 39 Ky.R. 1753; 2175; 2312; eff. 6-19-2013.)

## **201 KAR 2:076. Parenteral pharmaceutical compounding.**

RELATES TO: KRS 315.020

STATUTORY AUTHORITY: KRS 315.020(1), (2), 315.065(1), (2), 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is responsible to insure minimum standards of practice of parenteral compounding by pharmacies. The board is also responsible to insure the safety of all products provided to the citizens of the Commonwealth.

Section 1. A policy and procedure manual for parenteral pharmaceutical compounding shall be available at a pharmacy for inspection purposes. The manual shall include policies and procedures for:

- (1) Oncology drugs;
- (2) Disposal of unused supplies and medications;
- (3) Drug destruction and return;
- (4) Drug dispensing;
- (5) Drug labeling;
- (6) Storage;
- (7) Duties and qualifications for staff;
- (8) Equipment;
- (9) Handling of hazardous wastes;
- (10) Investigation drug protocol;
- (11) Safety;
- (12) Recordkeeping;
- (13) Reference material;
- (14) Sanitation;
- (15) Security;
- (16) Transportation; and
- (17) Quality assurance, as relates to:

- (a) Recall procedures;
- (b) Storage and dating;
- (c) Educational procedures for staff and patient;
- (d) Sterile procedures, to include routine maintenance and hood certification; and, if necessary,
- (e) Sterile testing of end products, operator procedures, and environment.

The manual shall be reviewed and revised on an annual basis.

Section 2. The following physical requirements are in addition to other requirements set forth in KRS 217.055 and 315:020:

- (1) The licensed pharmacy shall have a designated area for preparing compounded parenteral pharmaceuticals. This area shall be designed to withstand routine disinfecting procedures and shall be kept free of particulate generators, e.g., corrugated cardboard containers. This area shall be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The minimum equipment shall be:
  - (a) Laminar airflow hood or Class 100 clean room;
  - (b) Sink with hot and cold running water which is convenient to the compounding area;
  - (c) Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic and hazardous wastes from preparation of said agents;
  - (d) A Class II vertical flow biological safety cabinet, if oncology agents are prepared;
  - (e) Refrigerator or freezer with a thermometer; and
  - (f) A temperature controlled delivery container (not required if delivered in the same facility).
- (3) The minimum supplies shall be:
  - (a) Disposable needles, syringes, and other supplies needed for aseptic parenteral compounding;
  - (b) Disinfectant cleaning solutions;
  - (c) Hand-washing agent with bactericidal action;
  - (d) Disposable, lint-free towels or equivalent;
  - (e) Appropriate filters and filtration equipment;
  - (f) Oncology drug spill kit; and
  - (g) Disposable gowns, and sterile disposable gloves.
- (4) This area of the pharmacy shall not be accessible to the public and no one shall have access without supervision of the pharmacist.
- (5) The pharmacy shall have current reference materials related to sterile products.

Section 3. Each licensed pharmacy shall be managed by a pharmacist licensed to practice pharmacy in the Commonwealth and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. The pharmacist in charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. The pharmacist shall also be responsible for the development and

continuing review of all policies and procedures, training manuals, and the quality assurance programs, as well as participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness. The pharmacist in charge may be assisted by additional personnel adequately trained in this area of practice. A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and other health professionals' questions and needs.

#### Section 4.

(1) The pharmacist shall receive a written or verbal prescription or direct copy order from a prescriber before dispensing any compounded, sterile parenteral product.

These prescriptions or direct copy orders shall contain the following:

- (a) Patient's name;
- (b) Patient's address on controlled substances prescriptions or location (room number);
- (c) Drug name and strength;
- (d) Directions for use;
- (e) Date;
- (f) Authorized prescriber's name;
- (g) Prescriber's address and DEA number, if applicable;
- (h) Refill instructions, if applicable; and
- (i) Dispensing quantity, if applicable.

(2) A pharmacy generated profile shall be maintained separate from the prescription file. The patient profile shall be maintained under the control of the pharmacist in charge for a period of two (2) years following the last dispensing activity. In addition, a medication administration record (MAR) as part of the medical record shall be retained for a period of five (5) years from date of the patient's discharge from the facility, or in the case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longer. Supplemental records may also be employed as necessary. The patient profile shall contain:

- (a) Patient's name;
- (b) Sterile product dispensed;
- (c) Date dispensed;
- (d) Drug content and quantity; and
- (e) Patient's directions.

(3) Each sterile pharmaceutical dispensed to patients shall be labeled with the following information:

- (a) Name, address, and telephone number of the licensed pharmacy, if product will leave the premises;
- (b) Date;
- (c) Identifying number;
- (d) Patient's full name;
- (e) Name of each drug, strength, and amount;
- (f) Directions for use, including infusion rate;
- (g) Required controlled substances transfer warnings, where applicable;
- (h) Expiration date;
- (i) Identity of dispensing pharmacist;
- (j) Storage requirements, when applicable; and
- (k) Auxiliary labels, when applicable.

(4) The pharmacist in charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety, and welfare. Records shall be readily available, maintained for two (2) years at facility not computerized, but for five (5) years at facility utilizing computerized recordkeeping, and subject to inspection by the Board of Pharmacy or its agents. These shall include the following:

- (a) Patient profile;
  - (b) Purchase records;
  - (c) Biennial controlled substances inventories;
  - (d) Policy and procedures manual;
  - (e) Policies and procedures for cytotoxic wastes, if applicable;
  - (f) Quality assurance records; and
  - (g) Such other records and reports as may be required by law and rules and administrative regulations of the Kentucky Board of Pharmacy. Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's records. Release of this information shall be in accordance with federal and state laws.
- (5) The pharmacist in charge shall be responsible for the environmental control of all products shipped. Any compounded, sterile pharmaceutical that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product leaves the premises.
- (6) The pharmacist in charge shall be responsible for assuring that there is a system for the disposal of hazardous waste in a manner that does not endanger the public health.
- (7) A quality assurance program documented by the pharmacist shall be available to provide accountability for the manufacturing and distribution of sterile parenteral products.

Section 5. Licensed pharmacies that prepare oncology agents shall meet the following additional requirements in order to insure the protection of the personnel involved:

- (1) All oncology agents shall be compounded in a vertical flow, Class II, biological safety cabinet, and other products may be compounded in this cabinet;
- (2) Protective apparel shall be worn by personnel compounding oncology drugs, and this shall include disposable gloves and gowns;
- (3) Proper aseptic and safety techniques shall be used by personnel compounding oncology agents;
- (4) Appropriate disposable procedures for cytotoxic waste shall be developed that comply with applicable state and federal regulations;
- (5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed; and
- (6) Prepared doses of oncology drugs shall be dispensed, shipped, or delivered in a manner to minimize the risk of accidental rupture of the primary container and labeled with a distinctive cautionary label as being hazardous.

Section 6. There shall be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. Quality assurance procedures, at a minimum, shall include:

- (1) Recall procedures;



- (2) Storage and dating;
- (3) Educational procedures for staff;
- (4) Sterile procedures;
- (5) Hood or clean room annual certification by an independent contractor in accordance with federal standard 209B and NSF standard No. 49;
- (6) Prefilter cleaning and replacement when appropriate;
- (7) Justification of the chosen expiration dates for compounded parenteral products; and
- (8) Documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

Section 7. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121.

(16 Ky.R. 1716; Am. 2152; 2652; eff. 6-10-90.)

**201 KAR 2:080. Prescription substitution.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.191(2)

NECESSITY, FUNCTION, AND CONFORMITY: Although KRS 217.819 permits the exercise of product selection when there is no prohibition for such selection listed in the nonequivalent drug product formulary, this administrative regulation protects the public and practitioners in assuming that the medications and drugs dispensed are acceptable.

Section 1. Except as provided in KRS 217.822, whenever any registered pharmacist is requested to sell, furnish, or compound any drug, medicine, chemical or pharmaceutical preparation by means of a prescription and substitutes or causes to be substituted therefore, any other drug, medicine, chemical, or pharmaceutical preparation without specific or express permission, approval, or consent of the prescriber, the board may find such person guilty of engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public, and may revoke or suspend his license as prescribed by law.

Section 2. If approval or consent is obtained from the prescriber, the brand name or the name of the manufacturer of the drug, medicine, chemical or pharmaceutical preparation dispensed must be stated on the prescription by the pharmacist.

(Rx-8; 1 Ky.R. 147; eff. 12-11-74; Am. 16 Ky.R. 796; eff. 1-12-90.)

**201 KAR 2:090. Reference material and prescription equipment.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.19(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035(6) authorizes the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice. This administrative regulation establishes the minimum reference material and equipment required for pharmaceutical practice.

Section 1.

- (1) A pharmacy located within the Commonwealth that receives a pharmacy permit shall be required to maintain at least one (1) current reference from each of the following categories:

- (a) Category I - Pharmacology;
  - (b) Category II - Drug Interactions;
  - (c) Category III - Drug Product Composition; and
  - (d) Category IV - State and Federal Laws and Regulations.
- (2) References shall be relevant to the professional practice of pharmacy at the permitted pharmacy.
- (3) Electronic references shall be acceptable if the information is readily retrievable such that the pharmacist is not required to exit the dispensing program to obtain information from the electronic references. The existence of drug information on the Internet and the mere ability of the pharmacist to connect to the Internet shall not be sufficient to meet the requirements of this administrative regulation.

## Section 2.

- (1) The following shall be deemed as minimum equipment required of a pharmacy:
- (a) A prescription balance with a sensitivity not less than that of a Class 3 balance;
  - (b) Weights - metric or apothecary - complete set;
  - (c) Graduates capable of accurately measuring from 1 ml to 250 ml;
  - (d) Mortars and pestles - glass, porcelain, or wedgewood;
  - (e) Spatulas - steel and nonmetallic;
  - (f) Filtration funnel with filter papers;
  - (g) A heating unit;
  - (h) Suitable refrigeration unit for proper storage of drugs; and
  - (i) Ointment slab or ointment papers.
- (2) All equipment shall be maintained in a clean condition.

Section 3. The pharmacy shall have other reference material and equipment as dictated by experience to meet the needs of the particular pharmacy and necessary to compound and dispense in a safe manner.

Section 4. A pharmacy may be granted an exemption to required reference material and prescription equipment upon written petition to the board.

Section 5. The prescription counter upon which prescriptions are dispensed shall be used for the prime purpose of dispensing prescriptions. All pharmacies shall comply with all sanitation laws and administrative regulations.

(Rx-10; 1 Ky.R. 147; eff. 12-11-74; Am. 10 Ky.R. 890; eff. 4-13-84; 1444; 1792; eff. 2-7-2002.)

## **201 KAR 2:095. Dispensing responsibilities.**

RELATES TO: KRS 315.010(19), (25), 315.020, 315.050

STATUTORY AUTHORITY: KRS 315.020(4), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations necessary to regulate and control the practice of pharmacists. This administrative regulation establishes the professional responsibilities of a pharmacist and a pharmacist intern under supervision.

Section 1. Pursuant to KRS 315.020(4), a pharmacist intern shall perform professional acts within the practice of pharmacy under the immediate supervision and direction of a registered pharmacist.

Section 2. A pharmacist intern who has successfully completed his first professional year coursework of a Bachelor's of Science in Pharmacy or Doctor of Pharmacy degree program at an accredited school or college of pharmacy may, at the discretion of the supervising pharmacist, engage in delegated acts of professional practice pursuant to supervision as defined by KRS 315.010(25).

Section 3. A pharmacist shall be responsible for all the actions of the pharmacist intern.  
(Rx-12; 1 Ky.R. 718; Am. 2 Ky.R. 172; eff. 9-10-75; 11 Ky.R. 1615; eff. 6-4-85; 26 Ky.R. 1118; eff. 12-15-99.)

## **201 KAR 2:100. Security and control of drugs and prescriptions.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is authorized by KRS 315.191(1) to adopt rules and administrative regulations necessary to regulate and control pharmacists and pharmacies. This administrative regulation is to assure adequate security and control of drugs and prescriptions.

Section 1. A pharmacy must provide adequate security and control of its controlled substances and prescription legend drugs and in the absence of a pharmacist the pharmacy must be closed. If a pharmacy is located within a larger establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy must be enclosed by a floor to ceiling partition which may be either solid or solid transparent secured by lock from other departments of the store. In the absence of a pharmacist such pharmacies must be locked and secured. Employees of the establishment cannot be authorized to enter the closed pharmacy during those hours when a pharmacist is not present. Owners of prescription departments, which are to be closed at times the merchandise area of the same establishment remains open, must request permission from the Kentucky Board of Pharmacy, submit a detailed plan of the prescription department barrier and obtain written approval before enclosing the prescription department.

Section 2. All prescription files, all legend drugs and other items which are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

Section 3. Written prescription orders and refill requests can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription order(s) must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drug box" such that the prescription order is stored in the pharmacy area.

Section 4. Prepared prescription medications shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place. Emergency drugs shall be available throughout a hospital as deemed necessary by the pharmacist and under the overall control of the pharmacist. A night drug cabinet shall be maintained for the provision of emergency drugs in the absence of a pharmacist.

Section 5. It shall be regarded as unprofessional conduct under KRS 315.121(1)(f) for any pharmacist or employer of pharmacists to refrain from reporting to the board a pharmacist who:

- (1) Has been convicted of a misdemeanor or felony which involved acts that bear directly on the qualifications or ability of the applicant or licensee to practice pharmacy; or
- (2) Commits fraud or deceit in procuring or attempting to procure a license to practice pharmacy; or
- (3) Negligently or willfully acts in a manner inconsistent with the practice of pharmacy or willfully repeatedly violates any provisions of this chapter; or
- (4) Has a license to practice as a pharmacist denied, limited, suspended, probated or revoked in another jurisdiction on grounds sufficient to cause a license to be denied, limited, suspended, probated or revoked in this Commonwealth; or
- (5) Is practicing pharmacy without a current active license issued by the board.

(Rx-13; 1 Ky.R. 718; Am. 2 Ky.R. 173; eff. 9-10-75; 11 Ky.R. 1615; eff. 6-4-85.)

## **201 KAR 2:105. Licensing and drug distribution requirements for wholesale distributors.**

RELATES TO: KRS 315.010, 315.402, 315.406

STATUTORY AUTHORITY: KRS 315.010, 315.191(1), 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.402 and 315.406 authorizes the board to promulgate administrative regulations to regulate wholesale distributors of drugs. This administrative regulation establishes the requirements for the regulation of wholesale distributors.

Section 1. Definition. "Drug sample" means unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

### **Section 2. Requirements.**

- (1) A wholesale distributor engaged in wholesale distribution in the Commonwealth shall apply for a license from the board in accordance with KRS 315.402, 315.406, and this administrative regulation.
- (2) A separate license shall be required for each wholesale distributor's facility that distributes within the Commonwealth regardless of whether joint ownership or control exists.
- (3) An agent or employee of a licensee shall not be required to obtain a license under this section when the agent or employee is acting in the usual course of business or employment.
- (4) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:
  - (a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;

- (b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled merchandise until they are destroyed or returned;
- (c) Providing accurate and precise records of all goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction; and
- (d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and shall comply with all DEA regulations.

### Section 3. Qualifications for License.

- (1) The minimum qualifications shall include:
  - (a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the Commonwealth:
    - 1. Any convictions of the applicant under any federal, state, or local laws relating to drug samples and wholesale or retail drug distribution of controlled substances;
    - 2. Any felony convictions of the applicant under federal, state, or local laws;
    - 3. The applicant's past experience in the wholesale distribution of prescription drugs, including controlled substances;
    - 4. The furnishing by the applicant of false or fraudulent material in any application made in connection with wholesale distribution;
    - 5. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for wholesale distribution of any drugs, including controlled substances;
    - 6. Compliance with the requirements under any previously granted license or permit, if any; and
    - 7. Compliance with requirements to maintain or make available to the Kentucky Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section.
  - (b) The Kentucky Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest based on health and safety considerations.
- (2) A license shall not be issued pursuant to this administrative regulation unless the applicant has furnished proof satisfactory to the Board of Pharmacy:
  - (a) That the applicant is in compliance with all applicable federal and state laws and regulations relating to drugs; and
  - (b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in his application.
- (3) A license issued pursuant to this administrative regulation may be suspended or revoked for failure to comply with the provisions of KRS 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation.

### Section 4. Application, Fees, Renewals.

- (1) An application for a license shall be submitted to the Board of Pharmacy on "Application for a License to Operate as a Wholesale Distributor (KBP W 9:08)".

- (2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.
- (3) An application shall include:
- (a) The name, full business address, and telephone number of the licensee;
  - (b) All trade or business name used by the licensee;
  - (c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
  - (d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);
  - (e) The name(s) of the owner and operator of the licensee, including;
    - 1. If a person, the name and Social Security number of the person;
    - 2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;
    - 3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
    - 4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity; and
  - (f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.
- (4) All licenses shall:
- (a) Expire on September 30 following date of issuance; and
  - (b) Be renewable annually thereafter upon renewal application accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

## Section 5. Standards.

- (1) Facilities.
- (a) All buildings in which legend drugs are held for wholesale distribution, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.
  - (b) Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.
  - (c) A facility shall not be located in a residence.
- (2) Security.
- (a) A wholesale distributor shall be equipped with an alarm system to detect entry after hours.
  - (b) A wholesale distributor shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.
  - (c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

- (d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs.
- (3) Recordkeeping.
- (a) Inventories and other records of transactions regarding the receipt and disposition of legend drugs shall be maintained and readily available for inspection or photocopying by authorized law enforcement officials for a period of two (2) years following disposition of the drugs. These records shall include:
1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
  2. The identity and quantity of the drugs received and distributed or disposed of; and
  3. The dates of receipt and distribution or other distribution of the drugs.
- (b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.
- (4) Written policies and procedures.
- (a) A Wholesaler Distributor distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to assure that the wholesale distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.
- (b) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.
- (c) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the wholesale distributor's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.
- (d) There shall be written policies and procedures by which the wholesale distributor exercises control over the shipping and receiving of all stock within the operation.
- (5) Returned, damaged, and outdated prescription drugs. A wholesale distributor shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods if conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality,

or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A wholesale distributor shall maintain and follow written policy for handling recalls and withdrawals of products. The policy shall cover all recalls and withdrawals of drug products due to:

- (a) Any voluntary action on the part of the manufacturer;
  - (b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and
  - (c) Replacement of existing merchandise with an improved product or new package design.
- (7) (a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.
- (b) Procedures for distribution of approved stock shall provide for a rotation whereby the oldest inventory is distributed first.
- (c) A wholesale distributor shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

#### Section 6. Pedigree.

(1) Effective July 1, 2009 and in accordance with KRS 315.406, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(2) The pedigree shall include the following information concerning the prescription drug:

- (a) The proprietary and established name of the prescription drug;
  - (b) The dosage;
  - (c) The size of the container;
  - (d) The number of containers;
  - (e) The lot number of control number of the prescription drug;
  - (f) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
  - (g) The date of each previous transaction.
- (3) Pedigree records shall be maintained and readily be available for inspections or photocopying by authorized law enforcement officials for a period of two (2) years.

#### Section 7. Violations.

(1) A wholesale distributor shall not distribute legend drugs directly to a consumer or a patient or operate in a manner that endangers the public health.

(2) Violation of any of these provisions shall be grounds for the suspension or revocation of the license.

#### Section 8. Incorporation by Reference.

(1) "Application for a License to Operate as a Wholesale Distributor" (KBP W 9:08) is incorporated by reference.



(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, Spindletop Administration Building Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511, Monday through Friday, 8 a.m. to 4:30 p.m. \*

(9 Ky.R. 77; eff. 8-11-1982; Am. 11 Ky.R. 1616; eff. 6-4-85; 16 Ky.R. 1597; eff. 4-12-90; 18 Ky.R. 2348; 2832; 2917; eff. 3-25-92; 19 Ky.R. 445; eff. 10-8-92; 28 Ky.R. 2406; 29 Ky.R. 98; eff. 7-15-2002; 35 Ky.R. 982; 1826; 1740; eff. 2-18-2009.)

\* PLEASE NOTE: The Board's address has changed since this regulation went into effect. The current address for the Board is The Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601.

## **201 KAR 2:106. Pharmacy, manufacturer, or distributor closures.**

RELATES TO: KRS 315.035, 315.036

STATUTORY AUTHORITY: KRS 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. This administrative regulation establishes requirements relating to closure of business by licensees.

Section 1. Definitions. As used in this administrative regulation:

- (1) "Permanent closure" means a licensee:
  - (a) Ceases to do business and permanently closes; and
  - (b) Does not file application for a pharmacy license for the same location;
- (2) "Voluntary closure" means a closing or abandonment of premises resulting from:
  - (a) Chronic mental or physical deterioration; or
  - (b) A deviation from the business hours listed on the current permit application or amendments filed thereto; or
  - (c) Cessation of the practice of pharmacy at the licensed location for a reason other than permanent or involuntary closure.
- (3) "Involuntary closure" means an interruption of formal business activity resulting from:
  - (a) Acute illness or incapacitation;
  - (b) Death;
  - (c) Fire, flood or other natural disaster;
  - (d) Bankruptcy proceedings; or
  - (e) Court, government, or Board of Pharmacy action.

Section 2. Procedures for Closure.

- (1) Permanent closure.
  - (a) A licensee shall conspicuously place a sign notifying the public thirty (30) days in advance of the:
    1. Termination date of business; and
    2. Name and address of the licensee to which prescription files or other pertinent records will be transferred.
  - (b) Except when prevented by the exercise of another party's legal rights:
    1. The sign shall remain in place for a period of thirty (30) days after the closure; and
    2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

- (c) A licensee shall inform the Board of Pharmacy, Drug Enforcement Administration, and the Cabinet for Human Resources by written notice fifteen (15) days prior to the anticipated closing and include the following information:
    - 1. Date of business termination; and
    - 2. Name, address, and DEA number of registrant to whom the prescription or controlled drugs are to be transferred.
  - (d) In the absence of directives to the contrary from the Drug Enforcement Administration, the Board of Pharmacy, or the Cabinet for Human Resources, the transfer shall be effected on the assigned date.
  - (e) The transferor and the transferee shall each maintain copies of the following documents relating to transferred controlled substances for at least two (2) years:
    - 1. U.S. Official Order Forms, DEA-222 Schedule II; and
    - 2. Schedules III, IV, and V Invoices) for a period of at least two (2) years.
  - (f) Upon termination, a licensee shall:
    - 1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and
    - 2. Return the voided permits, the Drug Enforcement Administration registration, and unused Schedule II Order Forms to their respective office of issue.
  - (g) The posting of the sign required by paragraph (a) of this subsection shall not be required if:
    - 1. An application for a pharmacy license for the same location is filed; or
    - 2. During a sale of a pharmacy, prescription records are transferred to another permitted pharmacy that is within five (5) miles of the location of the pharmacy that is sold and owned by the purchasing entity.
- (2) Voluntary closure.
- (a) A pharmacy or distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.
  - (b) Upon receipt of the notice, the Board of Pharmacy, with full cooperation of the licensee, shall make arrangements it deems necessary to provide adequate and continued security and control of all drugs, chemicals, poisons, and devices owned or controlled by the licensee.
  - (c) If normal operation cannot resume within sixty (60) days, or if satisfactory agreements cannot be reached between the Board of Pharmacy, the licensee, or his designated representative, the:
    - 1. Permit shall be revoked; and
    - 2. Board of Pharmacy shall notify the Cabinet for Human Resources to assume control and responsibility of any drug, chemical, poison, or device deemed necessary in any manner deemed appropriate.
  - (d) If the Board of Pharmacy or the Cabinet for Human Resources or its agents liquidate or arrange for the liquidation of items specified in paragraphs (b) and (c) of this subsection, the board or the Cabinet for Human Resources may retain a portion of the proceeds realized from the liquidation equal to the expenses incurred.
- (3) Involuntary closure.

(a) Within five (5) days of involuntary closure, a licensee, or person authorized to act on his behalf, shall:

1. Notify the board in writing; and
2. Guarantee the safety and control of the licensed premises in a manner that will allow continued storage of controlled substances consigned to the board permittees for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee shall effect arrangements for the lawful sale or other disposition of drugs and substances requiring board licensure.

(c) The board may assume control and responsibility of substances it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A sale or other disposition has not been effected; or
2. An agreement between the board, and the licensee or person authorized to act on behalf of the licensee, has not been reached.

Section 3. Duties and Responsibilities of Licensee. A licensee or person authorized to act on his behalf shall:

- (1) Fully cooperate with the board to promote the efficient administration of action required by the provisions of this administrative regulation; and
- (2) Be financially liable to the board for expenses incurred by the board in its implementation of the provisions of this administrative regulation.

(16 Ky.R. 1718; Am. 2123; eff. 4-12-90; 23 Ky.R. 3866; 24 Ky.R. 61; eff. 6-18-97.)

### **201 KAR 2:115. Controlled release tablets, capsules and injectables.**

RELATES TO: KRS Chapter 217

STATUTORY AUTHORITY: KRS 217.814(7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a nonequivalent drug product formulary of drugs which should not be interchanged by pharmacists. In conformance with the publication cited, "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations," this administrative regulation lists controlled release tablets, capsules and injectables as noninterchangeable.

Section 1. The following are determined to be noninterchangeable: controlled release tablets, capsules and injectables - these dosage forms are subject to bioavailability and bioequivalence difference, primarily because different manufacturers developing controlled release products for the same active ingredient do not employ the same approach to formulating their controlled release products. Approved controlled release products for which bioequivalence data are available and considered as meeting necessary bioequivalence requirements are exempted from this administrative regulation.

(9 Ky.R. 285; Am. 688; eff. 1-6-83.)

### **201 KAR 2:116. Drug products with therapeutic problems.**

RELATES TO: KRS 217.819

STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation lists drug products with active ingredients or

dosage forms with potential bioequivalence problems, drugs characteristically possessing a narrow therapeutic index, or categories of agents for which there is either documented evidence of inequivalent therapeutic effect or a potential for it based on differences in bioavailability.

Section 1. The following have been determined by the board to be noninterchangeable: drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration not to be therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations."

Section 2. The following have been determined by the board to be noninterchangeable unless the United States Food and Drug Administration considers them therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations":

- (1) Digitalis glycosides;
- (2) Antiepileptic drugs;
- (3) Antiarrhythmic agents;
- (4) Conjugated estrogens;
- (5) Esterified estrogens;
- (6) Warfarin anticoagulants;
- (7) Theophylline products; and
- (8) Thyroid preparations.

Section 3. "Approved Drug Products with Therapeutic Equivalence Evaluations," 11th Edition, 1991, U.S. Food and Drug Administration is incorporated by reference.

(16 Ky.R. 1720; Am. 2154; eff. 5-13-90; 17 Ky.R. 2212; 2725; eff. 4-5-91.)

### **201 KAR 2:160. Licensees; inactive status.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.065, 315.110, 315.120, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: Senate Bill 241 of the General Assembly, Commonwealth of Kentucky, Regular Session 1982, provided for changes in KRS Chapter 315. This necessitated requirements for licensees to be issued inactive status and for those who desire to apply for renewal of a license to return to active practice.

Section 1. A pharmacist may apply for inactive status by:

- (1) Completing annual renewal application; and
- (2) Paying annual fee for inactive status.

Section 2. Pharmacists maintaining an active license to practice in another state or jurisdiction are ineligible for inactive status in Kentucky.

Section 3. Pharmacists seeking relicensure from inactive to active status must fulfill the following requirements:

- (1) If the pharmacist has been inactive for no more than five (5) consecutive years, he must:
  - (a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.

- (b) Satisfy the board's continuing education requirements for each year of inactive status.
  - (c) Successfully complete a jurisprudence examination given by the board.
  - (d) Pay all cumulative annual renewal fees required for active licensees.
- (2) If a pharmacist has had inactive status for more than five (5) consecutive years, he must:
- (a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.
  - (b) Successfully complete a satisfactory examination before the board.
  - (c) Pay all cumulative annual renewal fees required of active licensees.

(9 Ky.R. 633; Am. 778; eff. 12-1-82.)

## **201 KAR 2:165. Transfer of prescription information.**

RELATES TO: KRS 217.215(2), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(f) authorizes the Board of Pharmacy to promulgate administrative regulations to control the transfer of prescription drug orders between pharmacists and pharmacies. This administrative regulation establishes the procedures by which a prescription may be transferred between pharmacies in the Commonwealth or between a pharmacy and an establishment located in a state or United States Territory or District outside the Commonwealth and similarly credentialed as a pharmacy by that state or U.S. Territory or District for the purpose of dispensing.

### **Section 1.**

- (1) The transfer of prescription information for any noncontrolled substance prescription for the purpose of refill dispensing may occur if:
- (a) It is orally communicated directly between two (2) pharmacists in the Commonwealth or between a pharmacist and an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District;
  - (b) It is made through an on-line real-time computer system that provides documentation of the presence of a pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District when the information is transferred;
  - (c) It is made through the use of a facsimile machine and all the information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District; or
  - (d) It is made through the use of voice recording technology and all information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District.
- (2) If in the Commonwealth the transferring pharmacist shall record the following information:
- (a) That the prescription is void;

- (b) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District to which it was transferred and the name of the pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District receiving the prescription information; and
  - (c) The date of the transfer and the name of the pharmacist transferring the information.
- (3) If in the Commonwealth the pharmacist receiving the transferred prescription shall record the following information:
- (a) That the prescription is a transfer;
  - (b) The date of issuance of the original prescription;
  - (c) The refill authorization on the original prescription;
  - (d) The date of original dispensing;
  - (e) The refill authorization remaining and the date of the last refill;
  - (f) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District and the original prescription number from which the prescription was transferred; and
  - (g) The name of the transferor pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District.
- (4) Both the original prescription and the transferred prescription shall be maintained for a period of five (5) years from the date of the last refill.
- (5) Pharmacies electronically accessing the same prescription record shall satisfy all information of a manual mode for a prescription transfer.

Section 2. The transfer of prescription information for a controlled substance prescription, except a Schedule II controlled substance, for the purpose of refill dispensing may occur if the transfer complies with the requirements of 21 C.F.R. 1306.25.

Section 3. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), and (g).

(9 Ky.R. 1264; eff. 6-1-83; Am. 16 Ky.R. 797; eff. 1-12-90; 25 Ky.R. 1944; 2545; eff. 5-19-99; 1445; 1793; eff. 2-7-2002; 37 Ky.R. 1328; eff. 2-4-2011.)

### **201 KAR 2:170. Computerized recordkeeping.**

RELATES TO: KRS 217.215, 217.216, 315.191

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1),(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.215(2) provides for the board to establish administrative regulations relating to the storage and retrieval of prescriptions records, including computerized recordkeeping. This administrative regulation provides standards for those desiring to use computerized recordkeeping.

Section 1. The following information shall be entered into the system:

- (1) All information pertinent to a prescription shall be entered into the system, including, but not limited to, each of the following:
  - (a) The prescription number;

- (b) The patient's name and address;
  - (c) The prescriber's name and address;
  - (d) The prescriber's Federal Drug Enforcement Administration number, if appropriate;
  - (e) Refill authorization;
  - (f) Any prescriber's instructions or patient's preference permitted by law or administrative regulation;
  - (g) The name, strength, dosage form, and quantity of the drug dispensed originally and upon each refill; and
  - (h) The date of dispensing of the prescription and the identifying designation of the dispensing pharmacist for the original filling and each refill.
- (2) The entries shall be made into the system at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that the data already entered may appear for the prescription or refill without reentering that data. Records that are received or sent electronically may be kept electronically. The dispensing pharmacist shall be responsible for the completeness and accuracy of the entries.
- (3) The original prescription and a record of each refill, if received written or oral, shall be preserved as a hard copy for a period of three (3) years and thereafter be preserved as a hard copy or electronically for no less than an additional two (2) years. The original prescription and a record of each refill, if received by facsimile, shall be preserved as a hard copy, the original electronic image, or electronically for a period of three (3) years and thereafter be preserved as a hard copy, the original electronic image, or electronically for no less than an additional two (2) years. The original and electronic prescription shall be subject to inspection by authorized agents. An original prescription shall not be obstructed in any manner.
- (4) The original prescription and a record of each refill, if received as an e-prescription, shall be preserved electronically for a period of no less than five (5) years. The electronic prescription shall be subject to inspection by authorized agents. An original prescription shall not may be obstructed in any manner.
- (5) The required information shall be entered into the system for all prescriptions filled at the pharmacy.
- (6) The system shall provide adequate safeguards against improper manipulation or alteration of the data.
- (7) The system shall have the capability of producing a hard-copy printout of all original and refilled prescription data as required in Section 1 of this administrative regulation. A hard-copy printout of the required data shall be made available to an authorized agent within forty-eight (48) hours of the receipt of a written request.
- (8) The system shall maintain a record of each day's prescription data as follows:
- (a) This record shall be verified, dated, and signed by the pharmacist(s) who filled those prescription orders either:
    - 1. Electronically;
    - 2. Manually; or
    - 3. In a log.
  - (b) This record shall be maintained for no less than five (5) years; and
  - (c) This record shall be readily retrievable and shall be subject to inspection by authorized agents.

(9) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription order and that the maximum number of refills is not exceeded. If the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

(10) Controlled substance data shall be identifiable apart from other items appearing in the record.

(11) The pharmacist shall be responsible to assure continuity in the maintenance of records throughout any transition in record systems utilized.

Section 2. A computer malfunction or data processing services provider's negligence shall not be not a defense against charges of improper recordkeeping.

Section 3. This administrative regulation is not applicable to the recordkeeping for drugs prescribed for and administered to patients confined as inpatients in an acute care facility.

(9 Ky.R. 1264; Am. 10 Ky.R. 4; eff. 6-1-1983; 38 Ky.R. 652; 1297; eff. 1-18-2012.)

### **201 KAR 2:175. Emergency/seventy-two (72) hour prescription refills.**

RELATES TO: KRS Chapters 217, 315

STATUTORY AUTHORITY: KRS 217.215(3), 315.191

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation sets out the conditions whereby a prescription may be refilled in an emergency situation and the prescriber is unavailable.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one (1) time emergency refill of up to a seventy-two (72) hour supply of the medication when:

- (1) The prescription refill is not for a controlled substance;
- (2) The medication is essential to the maintenance of life or to the continuation of therapy in chronic conditions;
- (3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort;
- (4) The pharmacist notes on the prescription record the date, the quantity dispensed, and his name or initials; and
- (5) In all situations an emergency refill must be followed by authorization from the prescriber for continued therapy.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(9 Ky.R. 1265; Am. 10 Ky.R. 5; eff. 6-1-83; 16 Ky.R. 798; eff. 1-12-90.)

### **201 KAR 2:180. Pharmacies sanitation.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.191(1), (5)



NECESSITY, FUNCTION, AND CONFORMITY: There is no existing uniform administrative regulation for which the Kentucky Board of Pharmacy can monitor a pharmacy for cleanliness. Existing administrative regulations pertain only to food handling facilities. The purpose of this administrative regulation is to provide the board with the authority to require standards for compliance.

Section 1. The designated pharmacy area(s) shall be used exclusively for the compounding and dispensing of drugs and other usual procedures incidental to compounding and dispensing of drugs. This area shall be maintained in a clean and sanitary condition, adequately lighted and ventilated.

Section 2. No compounding or dispensing of drugs shall be carried on in any room used as a dwelling or for usual household purposes.

Section 3. Hot and cold water shall be readily accessible. Adequate facilities, separate and distinct from toilets and washrooms, shall be provided for maintaining clean and sanitary conditions.

Section 4. All equipment used in the storage, compounding, and dispensing of drugs or medicines shall be kept in a clean and sanitary manner.

Section 5. Proper temperatures shall be maintained for compounding and dispensing of drugs and medicines. Controlled room temperatures shall be fifteen (15) to thirty (30) degrees Centigrade, fifty-nine (59) to eighty-six (86) degrees Fahrenheit. Refrigeration temperatures shall be two (2) to eight (8) degrees Centigrade, thirty-six (36) to forty-six (46) degrees Fahrenheit. Freezer temperatures shall be minus twenty (-20) to minus ten (-10) degrees Centigrade, minus four (-4) to fourteen (14) degrees Fahrenheit. Under nonspecific conditions, it is to be understood that the storage conditions include protection from moisture, freezing, and excessive heat.

Section 6. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(10 Ky.R. 951; eff. 2-1-84.)

## **201 KAR 2:185. Noncontrolled substance prescription drug refills.**

RELATES TO: KRS 215.191(f), (g), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215, 315.191(1)(f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010, 315.191 and 217.215(2) require the Board of Pharmacy to promulgate administrative regulations necessary to regulate the practice of pharmacists and the recordkeeping systems associated with prescriptions. This administrative regulation establishes the responsibilities of pharmacists and practitioners relating to prescription drug refills.

### **Section 1.**

(1) A pharmacist shall not refill a prescription for a noncontrolled substance prescription drug unless authorized by the prescribing practitioner.

(2) A pharmacist shall record all refills by writing the date of the refill together with his name or initials on the original prescription.

(3) If an alternate approved automated data processing system is used, refills and records shall be maintained in compliance with 201 KAR 2:170.

Section 2.

(1) The use of the terms "prn" and "ad lib" in relation to authorization for refilling prescriptions shall mean the prescription may be refilled for a maximum period of one (1) year from the date prescribed.

(2) After one (1) year from the date prescribed, the prescribing practitioner shall issue a new prescription.

Section 3. If the authorized refills are expressed solely as a number, the prescription shall be refilled for the authorized limit of refills within one (1) year of the date prescribed.

Section 4. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), (g).

(10 Ky.R. 951; eff. 2-1-84; Am. 25 Ky.R. 11945; 2546; eff. 5-19-99.)

**201 KAR 2:190. Return of prescription drugs prohibited.**

RELATES TO: KRS Chapters 217 and 315

STATUTORY AUTHORITY: KRS 315.010(5), 315.191(1), (5)

NECESSITY, FUNCTION, AND CONFORMITY: To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded.

Section 1. No pharmacy, pharmacist, or agent thereof shall accept for reuse or resale a prescription drug. This administrative regulation shall not apply to sealed/unopened unit dose, unit of use or tamper resistant drug packaging.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(10 Ky.R. 952; eff. 2-1-84; Am. 11 Ky.R. 1126; eff. 3-12-85; 16 Ky.R. 799; eff. 1-12-90.)

**201 KAR 2:205. Pharmacist-in-charge.**

RELATES TO: KRS 315.020, 315.0351, 315.191, 315.300, 315.335

STATUTORY AUTHORITY: KRS 315.020(1), 315.0351, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.020(1) and 315.0351(7) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

## Section 2. Duties and Responsibilities.

- (1) The pharmacist-in-charge shall be so designated in the application for a permit to operate a pharmacy and in each application for renewal of that permit thereafter.
- (2) A pharmacist shall not serve as a pharmacist-in-charge:
  - (a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and
  - (b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.
- (3) The pharmacist-in-charge shall be responsible for:
  - (a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;
  - (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;
  - (c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;
  - (d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:
    1. Employment of the pharmacist-in-charge;
    2. Employment of staff pharmacists; or
    3. Schedule of hours for the pharmacy;
  - (e) Making or filing of any reports required by state or federal laws and regulations;
  - (f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and
  - (g) Filing of any report of a theft or loss to:
    1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);
    2. The Department of the Kentucky State Police as required by KRS 315.335; and
    3. The board by providing a copy to the board of each report submitted.

## Section 3. Incorporation by Reference.

- (1) The following material is incorporated by reference:
  - (a) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 07/2012;
  - (b) "Application for Non-Resident Pharmacy Permit", Form 1, 07/2012;
  - (c) "Application for Resident Pharmacy Renewal", Form 2, 07/2012; and
  - (d) "Application for Non-Resident Pharmacy Permit Renewal", Form 2, 07/2012.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(19 Ky.R. 1018; Am. 1340; eff. 11-30-92; 27 Ky.R. 194; 738; eff. 9-11-2000; 39 Ky.R. 508; eff. 2-1-2013.)

**201 KAR 2:210. Patient records and patient counseling.**

RELATES TO: KRS 315.191(1), (5), (6), 42 C.F.R. Part 456

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (5), 42 C.F.R. Part 456

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1), (56), 42 CFR Part 456 mandates that pharmacists implement drug utilization reviews and provide patient counseling to those recipients of health-care benefits for which federal funds are allocated. This administrative regulation provides for this mechanism and broadens its magnitude by rendering this valuable service available to all Kentucky's citizenry, equitably.

**Section 1. Patient Records.**

- (1) (a) A patient record system shall, with the exercise of professional judgment, be maintained by a pharmacy for patients for whom prescriptive drug orders are dispensed at that pharmacy location.
- (b) A pharmacist, with the exercise of professional judgment, shall establish a procedure for obtaining, recording, and maintaining information required for a patient record.
- (c) A pharmacist, or his designee, shall obtain, record, and maintain the information for a patient record.
- (d) A patient record shall:
  1. Be readily retrievable by manual or electronic means;
  2. Enable the pharmacist to identify previously dispensed drugs and known disease conditions;
  3. Enable the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescriptive drug order; and
  4. Be maintained for not less than 180 days from the date of the last entry.
- (2) A patient record shall include:
  - (a) Full name of patient for whom the drug is intended;
  - (b) Address and telephone number of the patient;
  - (c) Patient's age or date of birth;
  - (d) Patient's gender;
  - (e) A list of all prescriptions obtained by the patient at that pharmacy location for the past twelve (12) months by:
    1. Prescription number;
    2. Name and strength of medication;
    3. Quantity;
    4. Date received;
    5. Identity of prescriber; and
    6. Comments or other information as may be relevant to the specific patient or drug; and
  - (f) Individual medical history if significant, including known disease states, known allergies, idiosyncrasies, reactions or conditions relating to prospective drug use and drug regimen reviews.

**Section 2. Patient Counseling.**

- (1) The pharmacist shall offer to counsel a patient on matters which he believes will optimize drug therapy with each patient or caregiver:
  - (a) Upon the presentation of an original prescription order; and

- (b) On refill prescriptions, as professional discretion dictates.
- (2) (a) The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.
  - (b) If deemed impractical or inappropriate, the offer to counsel may be made:
    - 1. By the pharmacist designee;
    - 2. In written communication;
    - 3. By telephone through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange; or
    - 4. In another manner determined by the pharmacist to be appropriate.
- (3) Patient counseling shall be:
  - (a) In person when practical; or
  - (b) With reasonable effort, by telephone.
- (4) The pharmacist shall include the following elements of patient counseling that he has determined are appropriate:
  - (a) The name and description of the drug;
  - (b) The dosage form, dose, route of administration, and duration of therapy;
  - (c) Special directions and precautions;
  - (d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;
  - (e) Techniques for self-monitoring of drug therapy;
  - (f) Proper storage;
  - (g) Refill information;
  - (h) Action to be taken in event of a missed dose;
  - (i) His comments relevant to the individual's therapy; and
  - (j) Any other information peculiar to the specific patient or drug.
- (5) If a pharmacist determines that it is appropriate, he may supplement patient counseling with additional forms of patient information, such as:
  - (a) Written or printed information leaflets;
  - (b) Pictogram labels; and
  - (c) Video programs.
- (6) Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.

### Section 3. Confidentiality.

- (1) A patient record shall be held in confidence.
- (2) It shall be communicated or released:
  - (a) To the patient;
  - (b) As the patient directs; or
  - (c) As prudent, professional discretion dictates.

### Section 4. Prospective Drug Use Review.

- (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.
- (2) It shall include an assessment of a patient's drug therapy and the prescription order.

(3) A prospective drug use review shall include a review by the pharmacist of the following:

- (a) Known allergies;
- (b) Rationale for use;
- (c) Proper dose, route of administration, and directions;
- (d) Synergism with currently employed modalities;
- (e) Interaction or adverse reaction with applicable:
  - 1. Drugs;
  - 2. Foods; or
  - 3. Known disease states;
- (f) Proper utilization for optimum therapeutic outcomes; and
- (g) Clinical misuse or abuse.

#### Section 5. Documentation of Counseling.

- (1) A record that the patient refused the pharmacist's offer to counsel shall be maintained for one (1) year.
- (2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:
  - (a) The offer to counsel, as required in Section 2 of this administrative regulation, was made and accepted; and
  - (b) The counseling was provided.

#### Section 6. The provisions of this administrative regulation shall not apply:

- (1) To inpatients of a hospital or institution, if other licensed health-care professionals are authorized to administer the drugs; or
- (2) If there is documentation that the patient or caregiver refused consultation.

(19 Ky.R. 1694; eff. 2-17-93.)

### **201 KAR 2:215. Nuclear pharmacy services.**

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy shall be responsible for imposing minimum standards in all settings where drug products are dispensed and to ensure the safety of all drug products provided to the citizens of the Commonwealth. This administrative regulation applies to pharmacies as defined in KRS 315.010. The requirement of these administrative regulations are in addition to, and not in substitution of, other applicable administrative regulations promulgated by the Cabinet for Human Resources for radioactive materials and applicable administrative regulations promulgated by the Kentucky Board of Pharmacy.

#### Section 1. Definitions.

- (1) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.
- (2) "Radiopharmaceutical services" means those acts, services, operations and transactions necessary in the conduct, operation, management and control of a nuclear pharmacy, including, for example:
  - (a) The compounding, dispensing, labeling and delivery of radiopharmaceuticals;
  - (b) The participation in radiopharmaceutical utilization reviews; and
  - (c) The proper and safe storage and distribution of radiopharmaceuticals.

(3) "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(4) "Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, and it shall include, for example, internal test assessment, authentication of product history and the keeping of proper records.

(5) "Internal test assessment" means conducting those tests necessary to insure the integrity of the test.

(6) "Authentication of product history" means identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

(7) "Authorized practitioner" means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals. This person shall be named on a radioactive materials license issued by the Radiation Control Branch of the Cabinet for Human Resources.

(8) "Designated agent" means an individual who shall be under the direct supervision of an authorized practitioner and who shall be authorized to communicate that practitioner's instructions to a nuclear pharmacy.

(9) "Nuclear pharmacist" means a pharmacist licensed to practice in the Commonwealth of Kentucky and who meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Control Branch of the Cabinet for Human Resources.

(10) "Direct supervision" means that the supervising nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct in-process and final checks.

## Section 2. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(1) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a pharmacy operating under the direct supervision of a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the licensed area and in personal attendance at all times that the pharmacy is open for business.

(2) Nuclear pharmacies may be exempted from the general space requirements for pharmacies, but shall:

- (a) Have adequate space, commensurate with the scope of services required and meeting Radiation Control Branch, Cabinet for Human Resources, requirements established for all radioactive material licensees in the Commonwealth;
- (b) Be separate from the pharmacy areas for nonradioactive drugs;
- (c) Be inaccessible to all unauthorized personnel; and
- (d) Have a radioactive storage and decay area.

(3) The process used for handling radioactive materials by any license holder shall involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials as approved in a Kentucky radioactive materials license. In order to ensure the public health and safety in this respect, a nuclear pharmacy shall first meet the following general environmental requirements where the handling of radiopharmaceutical materials takes place:

- (a) Proper ventilation so that radioactive materials cannot be airborne from that environment to other nonoccupationally unrestricted areas;
- (b) Proper location so that the receipt and dispersal of radioactive materials do not result in inadvertent and undesired contamination of other nonoccupationally labeled areas; and
- (c) Proper design to allow radioactive materials to be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to ensure proper operation of the corresponding assay equipment.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with administrative regulations of the Radiation Control Branch of the Cabinet for Human Resources.

(5) A nuclear pharmacy, upon receiving an oral prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system, which writing or record shall contain at least the following:

- (a) The name of the authorized user or his agent;
- (b) The date of distribution and the time of administration of the radiopharmaceutical;
- (c) The name of the procedure;
- (d) The name of the radiopharmaceutical;
- (e) The dose or quantity of the radiopharmaceutical;
- (f) The serial number assigned to the order for the radiopharmaceutical;
- (g) Any specific instructions; and
- (h) The patient's name, whenever an order is for a therapeutic or blood-product radiopharmaceutical.

(6) The immediate outer container (shield) of a radioactive drug to be dispensed shall be labeled with the:

- (a) Standard radiation symbol;
- (b) Words, "Caution-Radioactive Material";
- (c) Radionuclide;
- (d) Chemical form;
- (e) Amount of radioactive material contained in millicuries or microcuries;
- (f) Volume in cubic centimeters, if a liquid;
- (g) Requested calibration time for the radioactivity contained;
- (h) Name, address, and telephone number of the nuclear pharmacy;
- (i) Prescription number;
- (j) Date; and
- (k) Space for patient's name.

(7) The immediate container shall be labeled with the:

- (a) Standard radiation symbol;
- (b) Words, "Caution-Radioactive Material";
- (c) Prescription number; and



- (d) Name of the radiopharmaceutical.
- (8) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.
- (9) A nuclear pharmacist may transfer to authorized persons, in accordance with the provisions of a Kentucky radioactive materials license, radioactive materials not intended for drug use and radiopharmaceuticals intended for individual patient use.
- (10) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing nonradioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Kentucky Board of Pharmacy may waive regulations pertaining to pharmacy licenses for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.
- (11) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.
- (12) Prescription orders for delivery of radioactive drugs for use in the medical practice of a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.
- (13)(a) A nuclear pharmacist in charge of a nuclear pharmacy shall have the authority to delegate to any qualified and properly trained person or persons, acting under his direct supervision, any nuclear pharmacy act which a reasonable and prudent nuclear pharmacist would find is within the scope of sound pharmaceutical judgment to delegate.
- (b) The delegation shall only occur if, in the professional opinion of the delegating nuclear pharmacist-in-charge, the act may be properly and safely performed by the person to whom the act is delegated.
- (c) The delegated act shall only be performed in its customary manner and not in violation of other statutes.
- (d) Persons to whom nuclear pharmacy acts are delegated shall not hold themselves out to the public as being authorized to practice pharmacy.

### Section 3. Minimum Requirements for Space, Equipment, Supplies, and Library.

- (1) Each nuclear pharmacy must meet the following requirements for space:
- (a) The area for the storage, compounding, and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;
  - (b) Hot lab and storage area shall be a minimum of 120 square feet; and
  - (c) The compounding and dispensing area shall be a minimum of 300 square feet.
- (2) Each nuclear pharmacy shall be equipped with at least the following items of equipment:
- (a) Dose calibrator;
  - (b) Refrigerator;
  - (c) Drawing station;
  - (d) Well scintillation counter;
  - (e) Microscope;

- (f) Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;
  - (g) Portable radiation survey meter; and
  - (h) Other equipment deemed necessary for radiopharmaceutical quality assurance for products compounded or dispensed as shall be determined by the Radiation Control Branch, Cabinet for Human Resources, and the Kentucky Board of Pharmacy.
- (3) Each nuclear pharmacy shall have on the premises current editions or revisions of the following reference materials:
- (a) United States Pharmacopedia-National Formulary with supplements;
  - (b) State statutes and administrative regulations relating to pharmacy;
  - (c) State and federal regulations governing the use of applicable radioactive materials; and
  - (d) Text relating to the practice of nuclear pharmacy and radiation safety.

Section 4. Radiopharmaceutical Quality Assurance. The holder of a nuclear pharmacy license shall be responsible for the radiopharmaceutical quality assurance of all radiopharmaceuticals, including biologicals, dispensed or manufactured.

(19 Ky.R. 1462; Am. 1742; eff. 1-27-93.)

## **201 KAR 2:220. Collaborative care agreements.**

RELATES TO: KRS 315.010(4), 315.040(4), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control matters relating to pharmacists, pharmacist interns, pharmacist technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes minimum requirements for the development and maintenance of collaborative care agreements between an individual pharmacist and an individual practitioner.

Section 1. A collaborative care agreement shall:

- (1) Be in writing;
- (2) Be signed and dated by the:
  - (a) Individual practitioner;
  - (b) Individual pharmacist; and
  - (c) Patient or care giver;
- (3) Provide that upon termination of the agreement the individual practitioner or individual pharmacist shall notify the patient in writing;
- (4) State the method for termination of the agreement; and
- (5) Contain the information specified by Section 2 of this administrative regulation.

Section 2. A collaborative care agreement shall contain the following information:

- (1) Patient name;
- (2) Patient address and telephone number;
- (3) Protocol, criteria, standing orders, or other method by which services are authorized;
- (4) The method established for the assessment of patient outcomes, if appropriate; and

- (5) Lab tests that may be ordered.

Section 3. The following information relating to a collaborative care agreement shall be maintained by a pharmacist and shall be provided to the collaborating practitioner:

- (1) Emergency notification contact;
- (2) Date of birth, weight, height, and gender;
- (3) Prescription regimen;
- (4) Nonprescription regimen;
- (5) Medical history; including:
  - (a) Known diseases;
  - (b) Known allergies; and
  - (c) Reactions and conditions relating to:
    1. Prescription regimens; and
    2. Nonprescription regimens;
- (6) Lab tests ordered, including results of lab tests;
- (7) Assessments of patient outcomes;
- (8) Notes relating to contacts between the individual pharmacist and the individual practitioner concerning the care and course of therapy of the patient; and
- (9) Documentation of the specific counseling information provided to the patient or care giver.

Section 4. A collaborative care agreement, and information and records required by the provisions of this administrative regulation, shall be maintained:

- (1) At the pharmacist's practice site; and
- (2) For at least five (5) years after termination.

(23 Ky.R. 3125; Am. 3807; 4109; eff. 6-16-97; 34 Ky.R. 2421; eff. 8-1-2008.)

### **201 KAR 2:225. Special pharmacy permit.**

RELATES TO: KRS 217.015(5)(a), 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those entities that distribute medical gasses.

#### **Section 1. Definitions.**

- (1) "Special pharmacy permits" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.
- (2) "Medical gasses" means oxygen United States Pharmacopoeia and nitrous oxide.

#### **Section 2. General Requirements.**

- (1) (a) An applicant for a special pharmacy permit for medical gasses shall comply with the requirements of 201 KAR 2:180 and 201 KAR 2:205, except that the pharmacist-in-charge designated on the special permit shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).
- (b) The pharmacist-in-charge shall review the records of the special pharmacy permit for medical gasses not less than once each quarter.

- (2) An applicant for a special pharmacy permit for medical gasses shall prepare and adopt a policy and procedures manual that sets forth a detailed description of how the:
- (a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and
  - (b) Licensee will maintain the premises so that the medical gasses remain secure and comply with applicable compendial monographs of official pharmacopoeias specified by KRS 217.015(5)(a).
- (3) An applicant for a special pharmacy permit for medical gasses shall be inspected by the board prior to the issuance of the license.

#### Section 3. Qualifications for License.

- (1) The board shall consider the following in reviewing the qualifications of an applicant for a special permit for medicinal gasses:
- (a) The applicant's experience in the sale or distribution of prescription drugs, including controlled substances;
  - (b) A felony conviction of the applicant under federal, state, or local laws;
  - (c) The furnishing by the applicant of false or fraudulent material in a previous application for:
    - 1. A special permit for medical gasses; or
    - 2. A federal or state medical assistance program;
  - (d) Suspension or revocation of an applicant's license or permit by federal, state, or local government; and
  - (e) Compliance with requirements under a previously granted license or permit.
- (2) The board shall deny an application for a special permit for medical gasses, if an applicant has:
- (a) Been convicted for a violation of federal, state, or local laws relating to:
    - 1. The practice of pharmacy;
    - 2. Drugs; or
    - 3. Federal or state medical assistance programs.
  - (b) Furnished false or fraudulent material in the application for a special permit for medical gasses;
  - (c) Failed to maintain or make available required records to the:
    - 1. Board; or
    - 2. Federal, state, or local law enforcement officials;
  - (d) Failed to comply with applicable federal, state, and local laws and regulations relating to medical gasses; or
  - (e) Failed to provide appropriate land, buildings, and security necessary to properly carry on the business described in his application.

#### Section 4. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special permit for medicinal gasses on "Application for Permit to Operate A Pharmacy In Kentucky"; and
- (2) As appropriate, the:
- (a) Initial application fee established by Section 1(10), 201 KAR 2:050; or
  - (b) Renewal fee established by Section 1(11), 201 KAR 2:050.

#### Section 5. Incorporation By Reference.

(1) "Application for Permit to Operate A Pharmacy In Kentucky (11/92)" is incorporated by reference.

(2) This form may be obtained, inspected, or copied at the Kentucky Board of Pharmacy, 1024 Capital Center Drive, Suite 210, Frankfort, Kentucky 40601-8204, 8 a.m. to 4:30 p.m., Monday through Friday.\*

(23 Ky.R. 4021; Am. 24 Ky.R. 329; eff. 7-16-97.)

\* PLEASE NOTE: The Board's address has changed since this regulation went into effect. The current address for the Board is The Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601.

**201 KAR 2:230. Special limited pharmacy - central refill pharmacy.**

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020 requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist.

KRS 315.035 requires that all pharmacies hold a permit issued by the board. This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those pharmacies that package, label and distribute refill prescriptions to pharmacies in the Commonwealth.

Section 1. Definition. "Central refill pharmacy" means a pharmacy located in the Commonwealth that provides packaging, labeling and delivery of a refill prescription product to another pharmacy for the purpose of the refilling of a valid prescription.

Section 2. The central refill pharmacy shall:

(1) Either:

(a) Have a written contract with the pharmacy which has custody of the original prescription authorization for refill dispensing; or

(b) Be under common ownership with that pharmacy;

(2) Prepare the label for the refill prescription product which clearly identifies the name and address of the pharmacy preparing the product for refill dispensing and the name and address of the pharmacy that will receive the prepared product for dispensing to the patient;

(3) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the preparation of the refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product;

(b) Pharmacy preparing the refilled prescription product; and

(c) Pharmacy to which the prepared refill prescription product is delivered;

(4) Provide the originating pharmacy with written information that describes how a patient may contact the central refill pharmacy if the patient has any questions about the preparation of the prescription refill; and

(5) Be responsible for ensuring that the order has been properly prepared and verified by a pharmacist.

Section 3. The pharmacy to which a prepared prescription refill product is delivered shall:

(1) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the receipt and dispensing of the centrally refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product prior to its dispensing; and

(b) Pharmacy preparing the refilled prescription product;

(2) Be responsible for ensuring that the refill has been properly prepared, packaged and labeled;

(3) Provide the patient with written information that described how a patient may contact either:

(a) The central refill pharmacy if the patient has any questions about the preparation of the prescription refill; or

(b) the dispensing pharmacy if the patient has any questions about the use of the medication; and

(4) Be responsible for adherence to the requirements of 201 KAR 2:210.

(26 Ky.R. 1735; Am. 2238; eff. 6-12-2000; 35 Ky.R. 1851; eff. 3-11-09.)

#### **201 KAR 2:240. Special limited pharmacy - charitable pharmacy.**

RELATES TO: KRS 315.035

STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020, 315.030, and 315.191(1)(a) requires the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

##### **Section 1. Definitions.**

(1) "Charitable organization" means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code.

(2) "Legend drug sample" means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.

(3) "Qualified indigent patient" means a patient of the charitable pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs.

##### **Section 2.**

(1) A charitable pharmacy:

(a) Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and

(b) May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.

(2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.

(5) A charitable pharmacy shall not:

(a) Accept controlled substances from pharmacies, wholesalers, or manufacturers; or

(b) Dispense controlled substances.

(6) A pharmacy that requests a charitable pharmacy permit shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy will maintain a separate and distinct prescription drug stock. The failure of either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit and the pharmacy permit.

(27 Ky.R. 254; Am. 739; eff. 9-11-2000.)

### **201 KAR 2:250. Pharmacist Recovery Network Committee.**

RELATES TO: KRS 315.121(1)(d), 315.126

STATUTORY AUTHORITY: KRS 315.126(3), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.126(1) requires the Board of Pharmacy to establish a pharmacy recovery network committee (PRNC). This administrative regulation establishes minimum requirements for the establishment and operation of the PRNC. This administrative regulation specifies the manner by which the board's PRNC consultant works with the board in intervention, evaluating and treating a pharmacist or intern, and providing for continuing care and monitoring by the consultant through a treatment provider.

Section 1. The board's Pharmacist Recovery Network Committee (PRNC) consultant shall be a pharmacist licensee of the board. The consultant shall assist the Case Review Committee (CRC) and the PRNC in carrying out their respective responsibilities. This shall include working with the board's inspectors and investigators to determine whether a pharmacist or intern is in fact impaired.

Section 2. If a pharmacist or intern self reports impairment as a result of the misuse or abuse of alcohol or drugs, or both; or if the board receives a legally sufficient complaint alleging that a pharmacist or intern is impaired as a result of the misuse or abuse of alcohol or drugs, or both, and no complaint against the pharmacist or intern other than impairment exists, the reporting of any impairment information to the board shall be forwarded to the consultant and shall not constitute grounds for discipline, if the PRNC finds the pharmacist or intern has:

(1) Acknowledged the impairment problem;

(2) Voluntarily enrolled in an appropriate, approved treatment program;

(3) Voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until the PRNC is satisfied the licensee has successfully completed an approved treatment program; and

(4) Executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant

shall not make copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

Section 3.

(1) A treatment provider shall disclose to the consultant or board if applicable all information in its possession regarding the issue of a pharmacist's or intern's impairment and participation in the treatment program. Failure of the treatment provider to provide information to the consultant shall be a basis for the withdrawal of the use of the program or provider.

(2) If in the opinion of the consultant or PRNC, an impaired pharmacist or intern has not progressed satisfactorily in a treatment or recovery program, all information regarding the issue of a pharmacist's or intern's impairment and participation in a treatment or recovery program in the consultant's possession shall be disclosed to the board. That disclosure shall constitute a complaint.

Section 4. All information concerning a pharmacist or intern held by the consultant, PRNC, CRC, or board shall remain confidential.

Section 5.

(1) The PRNC shall be comprised of eleven (11) members. The members shall include:

- (a) The President of the Board of Pharmacy;
- (b) The Chair of the PRNC;
- (c) The Executive Director of the Board of Pharmacy; and
- (d) Eight (8) other members, of which seven (7) shall be pharmacists and one (1) shall be a citizen member.

(2) (a) All members shall have the same rights, which include voting privileges.  
(b) A member of the PRNC shall not be on the board, except the President of the Board.

(c) Any criminal conviction or disciplinary action by a licensure board against a proposed member shall be reported to the board prior to consideration for appointment.

(d) There may be no more than four (4) members in successful recovery on the PRNC.

(e) A pharmacist under a Pharmacist Recovery Network Agreement shall not serve on the PRNC.

(3) (a) A PRNC member may be appointed by the board a maximum of three (3), four (4) year terms.

(b) A PRNC member shall not serve more than (2) terms consecutively.

(c) After serving two (2) consecutive terms a PRNC member shall rotate off the PRNC for at least two (2) years.

(d) A committee member shall serve no more than twelve (12) years on the PRNC.

(e) The President of the Board, the PRNC Consultant, and the Executive Director of the Board membership on the PRNC shall not constitute a twelve (12) year term.

(f) Membership of the PRNC shall be selected by the board from a list of qualified candidates submitted by an interested individual or entity.



(4) A member of the PRNC who becomes impaired, relapses, has any criminal conviction, or has any disciplinary action by a licensure board shall immediately resign from the PRNC.

(5) The board by majority vote, with the recusal of the President of the Board, may remove a member of the PRNC for any of the following reasons:

- (a) Refusal or inability of a committee member to perform duties as a member of the committee in an efficient, responsible, and professional manner;
- (b) Misuse of the committee by a member to obtain personal, pecuniary, or material gain or advantage for the member or others; and
- (c) Violation of any provision of KRS Chapter 315.

(28 Ky.R. 1517; Am. 1793; eff. 2-7-2002; 33 Ky.R. 4201; 34 Ky.R. 229; eff. 8-16-07.)

## **201 KAR 2:260. Automated Pharmacy System in Residential Hospice Facilities.**

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.295, 315.300, 216B3195

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295

NECESSITY, FUNCTION, AND CONFORMITY: KRS 335.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist.

KRS 315.295 authorizes the board to regulate an automated pharmacy system in a residential hospice facility. This administrative regulation establishes the standards for the operation of this type of system.

### **Section 1. Definitions.**

- (1) "Automated Pharmacy System" is defined by KRS 315.295(1)(a).
- (2) "Residential Hospice Facility" is defined by KRS 315.295(1)(b).

**Section 2. Responsibility.** The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for all of the following:

- (1) Assuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed and complying with the recordkeeping and security safeguards pursuant to Section 3 of this administrative regulation;
- (2) Assuring medications are reviewed by a pharmacist prior to access;
- (3) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures; and
- (4) Notifying the board with prior written notice of the installation or removal of an automated pharmacy system. This notification shall include the following:
  - (a) Name and address of pharmacy;
  - (b) Initial location of the automated pharmacy system. The automated pharmacy system may thereafter be relocated within the pharmacy or health care facility without providing subsequent notification to the board; and
  - (c) Pharmacist-in-charge.
- (5) Assigning, discontinuing or changing personnel access to the system;
- (6) Assuring that access to the medications comply with state and federal laws; and
- (7) Assuring that the automated pharmacy system is stocked accurately and that the automated pharmacy system stock is checked monthly in accordance with established written policies and procedures, including the following:
  - (a) Accuracy;

- (b) Integrity; and
- (c) Expiration date.

Section 3. Standards. An automated pharmacy system shall comply with the following provisions:

- (1) A pharmacy shall maintain on-site the following documentation relating to an automated pharmacy system:
  - (a) Name and address of the pharmacy or inpatient health care facility where the system is being used;
  - (b) The automated pharmacy system manufacturer's name, model, and serial number;
  - (c) Description of how the system is used;
  - (d) Written quality assurance procedures to determine continued appropriate use of the system; and
  - (e) Written policies and procedures for system operation, safety, security, accuracy, access and malfunction.
- (2) All written policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system.
- (3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.
- (4) Records and data kept by the automated pharmacy system shall meet the following requirements:
  - (a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and
  - (b) Records shall be maintained by the pharmacy and be available to the Board and shall include the following:
    - 1. The time and location of the system accessed;
    - 2. Identification of the individual accessing the system;
    - 3. Type of transaction;
    - 4. Name, strength, dosage form and quantity of drug accessed;
    - 5. Name of the patient for whom the drug was ordered;
    - 6. The prescription number;
    - 7. The name of the prescriber; and
    - 8. All events involving user database modifications shall be recorded electronically and maintained.
- (5) The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, pharmacist intern, or pharmacy technician, who shall be under the general supervision of a pharmacist on-site.
- (6) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.
- (7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.
- (8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) The automated pharmacy system shall provide a mechanism for securing and accounting for medications returned to the system and accounting for wasted medications in accordance with federal and state laws.

(3305; Am. 3602; eff. 6-20-2007.)

### **201 KAR 2:270. Expungement.**

RELATES TO: KRS 315.121(6), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.121(6), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to pharmacists. KRS 315.121(6) requires the board to promulgate administrative regulations to establish violations that are considered minor and subject to expungement. This administrative regulation establishes the violations considered minor and the criteria and procedure for expungement.

Section 1. Definition. "Expungement" means that:

- (1) The affected records shall be sealed;
- (2) The proceedings to which they refer shall be deemed not to have occurred; and
- (3) The affected party may properly represent that no record exists regarding the matter expunged.

Section 2. Minor Violations and Expungement Procedure.

- (1) The following violations are to be considered minor in nature:
  - (a) Failure to timely renew a license or permit;
  - (b) Failure to timely obtain required continuing education; and
  - (c) Failure to timely obtain required HIV/AIDS continuing education.
- (2) A pharmacist seeking expungement of a record of a disciplinary action resulting from a violation designated in subsection (1) of this section shall, in accordance with KRS 315.121(6):
  - (a) Not have been the subject of a subsequent violation of the same nature for a period of three (3) years after the date of completion of disciplinary sanctions imposed for the violation sought to be expunged; and
  - (b) Submit a written request to the board.
- (3) The board shall consider each request and shall, if the conditions of subsection (2) of this section are satisfied, expunge every record relating to the subject disciplinary order.

(29 Ky.R. 2196; Am. 2447; eff. 4-11-03.)

### **201 KAR 2:280. Prescription dispensing for formulary Compliance.**

RELATES TO: KRS 217.814, 315.191

STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between qualifying pharmacists and pharmacies. This administrative regulation establishes procedural and substantive requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval.

Section 1. Dispensing.

(1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways:

1. In the practitioner's own handwriting; or
2. By checking a "formulary compliance approval" box on a preprinted form;

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and

(c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.

(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

(a) That the pharmacist engaged in formulary compliance; and

(b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

(29 Ky.R. 2197; Am. 2447; eff. 4-11-03.)

**201 KAR 2:300. Common database.**

RELATES TO: KRS 315.020, 315.035, 315.0351

STATUTORY AUTHORITY: KRS 315.035, 315.0351, 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 and 315.0351 require that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.191(1)(a) and (f) authorize the Kentucky Board of Pharmacy to promulgate administrative regulations pertaining to pharmacies; pharmacists; and the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders. This administrative regulation establishes minimum requirements for prescription drug orders within and between pharmacists and pharmacies.

Section 1. Definition. "Common Database" means information shared among pharmacists and pharmacies for the purpose of dispensing medications or providing other forms of pharmacist care to a patient.

Section 2. The use of a common database shall not constitute a transfer as established in 201 KAR 2:165, provided that the following conditions are met:

(1) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall be under common ownership and utilize a common database;

(2) All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacies engaging in dispensing functions shall be properly permitted in Kentucky pursuant to KRS 315.035 or 315.0351.

(3) A pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky;

(4) The common database shall maintain a record of all pharmacists, pharmacist interns, and pharmacy technicians involved in the process of dispensing a prescription;

(5) The owner of the common database shall maintain a policy and procedure manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agents upon request within five (5) business days and which shall include:

- (a) A procedure detailing how each pharmacy and each pharmacist accessing the common database shall comply with applicable federal and state laws, rules, and regulations;
  - (b) The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board;
  - (c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and
  - (d) A quality assurance program designed to objectively and systemically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of a common database; and
- (6) A pharmacist dispensing a prescription shall at all times exercise independent professional judgment and shall be responsible for his or her actions and the professional actions of those individuals the pharmacist is required to supervise.

(34 Ky.R. 2252; 2390; eff. 6-6-2008.)

**201 KAR 2:310. Compounding for a practitioner's office or institutional administration.**

RELATES TO KRS 315.191(1)(a).

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation addresses compounding for use by a practitioner's office administration or institutional administration.

Section 1. A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug for a practitioner's office administration or institutional administration.

Section 2. A compounded drug that contains a controlled substance shall not be compounded for office or institutional administration.

Section 3. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.

Section 4. Label Requirements. A label shall be generated for the compounded drug and shall include:

- (1) The name of the practitioner;
- (2) The designated name and strength of the compounded drug;
- (3) The quantity dispensed;
- (4) A lot or batch number of the compounded drug;
- (5) The beyond use date for the compounded drug;

- (6) The date the compounded is dispensed;
- (7) The pharmacy's name, address, and telephone number;
- (8) Any special storage requirements;
- (9) A notation stating "For Office or Institutional Administration Only-Do Not Dispense to Patient";
- (10) Any auxiliary label required for the compounded drug.

Section 5. The compounded drug shall be administered in the practitioner's office or institution and shall not be dispensed to the patient.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.

(35 Ky.R. 1954; 2006; eff. 3-11-09.)

**201 KAR 2:320. Permit requirements for manufacturers.**

RELATES TO: KRS 315.020(2), 315.036, and 315.191(1)

STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.036 and 315.191(1) authorizes the board to promulgate administrative regulations to regulate the manufacturers of drugs. KRS 315.036 authorizes the board to promulgate administrative regulations regarding manufacturer permits and the maintenance and reporting of accurate records of all drugs manufactured, received and sold. KRS 315.020(2) authorizes the Board to promulgate administrative regulations regarding the pharmacist-in-charge. This administrative regulation establishes the requirements for a manufacturer permit and for functioning as a manufacturer.

**Section 1. Requirements.**

- (1) A manufacturer shall apply for a permit from the board in accordance with KRS 315.036 and this administrative regulation.
- (2) A separate permit shall be required for each facility within the Commonwealth regardless of whether joint ownership or control exists.
- (3) An agent or employee of a permit holder shall not be required to obtain a permit under this section when the agent or employee is acting in the usual course of business or employment.
- (4) A permit shall not be issued or renewed unless the applicant or its officers demonstrates or continues to demonstrate acceptable operational procedures, including:
  - (a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or current year United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;
  - (b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled merchandise until they are destroyed or returned;

- (c) Providing accurate and precise records of all goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction;
- (d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and compliance with all DEA regulations.

## Section 2. Qualifications for Permit.

- (1) (a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of prescription drugs within the Commonwealth:
  - 1. Any convictions of the officers of the applicant under any federal, state, or local laws;
  - 2. The applicant's past experience in the manufacture of prescription drugs, including controlled substances;
  - 3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing;
  - 4. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant or its officers for the manufacture of any drugs, including controlled substances;
  - 5. Compliance with the requirements under any previously granted license or permit, if any; and
  - 6. Compliance with requirements to maintain or make available to the Kentucky Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section.
- (b) The Kentucky Board of Pharmacy shall have the right to deny a permit to an applicant or its officers if it determines that the granting of that permit would not be in the public interest for any reason established in KRS 315.121.
- (2) A permit shall not be issued pursuant to this administrative regulation unless the applicant or its officers has furnished proof satisfactory to the Board of Pharmacy:
  - (a) That the applicant and its officers are in compliance with all applicable federal and state laws and regulations relating to drugs; and
  - (b) That the applicant and its officers are equipped as to land, buildings, and security to properly carry on the business described in the application.
- (3) A permitted manufacturer may sell or distribute federal legend drugs only to the following:
  - (a) A currently permitted manufacturer;
  - (b) A currently licensed wholesale distributor;
  - (c) A currently permitted pharmacy;
  - (d) A currently licensed practitioner;
  - (e) A currently licensed hospital, but only for use by or in that hospital; or
  - (f) A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes.
- (4) A permit holder may be disciplined for failure to comply with the provisions of KRS 315.036, pursuant to KRS 315.121, or this administrative regulation.

## Section 3. Application, Fees; Renewals.

- (1) An application for a permit shall be submitted to the Board of Pharmacy on Application for a Permit to Operate as a Manufacturer (KBP M 5:09).
- (2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.
- (3) An application shall include:
  - (a) The name, full business address, and telephone number of the applicant;
  - (b) All trade or business name used by the applicant;
  - (c) Addresses, telephone numbers, and the names of the contact persons for the facility used by the permittee for the storage, handling, and manufacturing of prescription drugs;
  - (d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);
  - (e) The name(s) of the owner and operator of the permittee, including:
    - 1. If a person, the name and Social Security number of the person;
    - 2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;
    - 3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
    - 4. If a sole proprietorship, the full name and social security number of the sole proprietor and the name of the business entity; and
  - (f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to manufacture or possess prescription drugs.
- (4) All permits shall:
  - (a) Expire on September 30 following the date of issuance; and
  - (b) Be:
    - 1. Renewable annually thereafter upon proper application accompanied by the renewal fee set forth in 201 KAR 2:050; and
    - 2. Nontransferable.

#### Section 4. Standards.

- (1) Facilities.
  - (a) All buildings in which legend drugs are repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.
  - (b) Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.
  - (c) A facility shall not be located in a residence.
- (2) Security.
  - (a) A manufacturer shall be equipped with an alarm system to detect entry after hours.
  - (b) A manufacturer shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.
  - (c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are



held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A permit holder shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the manufacture of prescription drugs.

(e) Lists of officers, directors, managers and other persons in charge of distribution, storage, and handling of prescription drugs, including a description of their duties and summary of their qualifications, shall be maintained for purpose of review.

(3) Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of legend drugs shall be maintained and readily available for inspection or photocopying by authorized law enforcement officials for a period of two (2) years following disposition of the drugs. These records shall include:

1. The source of the drugs including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;
2. The identity and quantity of the drugs received and distributed or disposed of; and
3. The dates of receipt and distribution or other distribution of the drugs.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(4) Written policies and procedures.

(a) A manufacturer shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to ensure that the manufacturer prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(b) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(c) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the manufacturer's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return or otherwise destroyed, and this shall be documented.

(d) There shall be written policies and procedures by which the manufacturer exercises control over the shipping and receiving of all stock within the operation.

(5) Returned, damaged, and outdated prescription drugs. A manufacturer's operation shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods. If conditions under which a prescription

drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the manufacturer shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A manufacturer shall adopt, maintain, and follow a written policy for handling recalls and withdrawals of products. The policy shall cover all recalls and withdrawals of drug products due to:

- (a) Any voluntary action on the part of the manufacturer;
  - (b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and
  - (c) Replacement of existing merchandise with an improved product or new package design.
- (7) (a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.
- (b) Procedures for distribution of approved stock shall provide for a rotation whereby the first expiration inventory is distributed first.
- (c) A manufacturer shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Section 5. Pharmacist-in-charge. A manufacturer shall designate a pharmacist-in-charge of the facility who shall be responsible to the board for security and recordkeeping. The pharmacist-in-charge shall review the security and records by conducting an on-site inspection not less than quarterly.

#### Section 6. Violations.

- (1) A drug manufacturer shall not distribute legend drugs directly to a consumer or a patient or operate in a manner that endangers the public health.
- (2) Violation of any of these provisions shall be grounds for the discipline of the permit pursuant to KRS 315.121.

#### Section 7. Incorporation by Reference.

- (1) "Application for a Permit to Operate as a Manufacturer", 6/09, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, Spindletop Administrative Building, Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511, Monday through Friday, 8 a.m. through 4:30 p.m. \*

(36 Ky.R. 618; Am. 778; eff. 10-21-09.)

\* PLEASE NOTE: The Board's address has changed since this regulation went into effect. The current address for the Board is The Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601.

**201 KAR 2:330. Emergency pharmacy powers.**

RELATES TO KRS 39A.100, 315.500

STATUTORY AUTHORITY: KRS 315.191, 315.505

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.500 establishes the conditions under which a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor pursuant to KRS 39A.100. 315.191 authorizes the Board of Pharmacy to promulgate administrative regulations governing pharmacists and pharmacies. This administrative regulation sets out the conditions whereby a prescription may be refilled pursuant to an executive order issued by the Governor as authorized by KRS 315.500 when the prescriber is unavailable. This administrative regulation sets out the conditions whereby a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor as authorized by KRS 315.500.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense an emergency refill of up to a thirty (30) day supply of the medication if:

- (1) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located;
- (2) The pharmacist obtains prescription information from:
  - (a) A prescription label;
  - (b) A prescription record within the pharmacy;
  - (c) A prescription record from another pharmacy;
  - (d) A common database;
  - (e) The patient; or
  - (f) Any other healthcare record;
- (3) The prescription refill is not for a controlled substance;
- (4) The prescription is for a maintenance medication;
- (5) In the pharmacist's professional judgment, the interruption of therapy may produce undesirable consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort; and
- (6) The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials.

Section 2.

- (1) A pharmacy may temporarily relocate to and operate at a new location if:
  - (a) It is not safe or practicable to operate a pharmacy at the address listed on the permit; and
  - (b) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located.
- (2) The pharmacy owner shall:
  - (a) Maintain confidentiality of patient records;
  - (b) Secure all drugs; and
  - (c) Notify the board of the temporary address as soon as practicable.
- (3) The following regulatory requirements shall not apply for this temporary location:
  - (a) The requirement to maintain references as listed in 201 KAR 2:090, Section 1;

- (b) The requirement to maintain equipment as listed in 201 KAR 2:090, Section 2; and
- (c) The requirement that the pharmacy be enclosed by a floor to ceiling partition if it is located within a larger establishment which is open to the public for business when a pharmacist is not present.

(37 Ky.R. 951; eff. 10-20-2010.)

**201 KAR 2:340. Special pharmacy permit for clinical practice.**

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 authorizes the Board of Pharmacy issue a permit to a pharmacy. KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services. This administrative regulation establishes the requirements for the special pharmacy permit for clinical practice.

Section 1. Definition. "Special pharmacy permit for clinical practice" means a permit issued to a pharmacy that maintains patient records and other information for the purpose of engaging in the practice of pharmacy and does not dispense prescription drug orders.

Section 2. General Requirements.

- (1) An applicant for a special pharmacy permit for clinical practice shall:
  - (a) Prepare and adopt a policy and procedure manual that is updated annually;
  - (b) Maintain pharmacy references as outlined in 201 KAR 2:090;
  - (c) Maintain a physical pharmacy address;
  - (d) Designate a Pharmacist-in-Charge (PIC) without a required minimum number of hours of physical presence;
  - (e) Maintain patient records for five (5) years in a manner that shall provide adequate safeguard against improper manipulation or alteration of the records; a computer malfunction or data processing services' negligence is not a defense against the charges of improper recordkeeping; and
  - (f) Maintain patient records by establishing:
    - 1. A patient record system to be maintained for patients for whom non-dispensing pharmacy services and functions are being performed;
    - 2. A procedure for obtaining, recording, and maintaining information required for a patient record by a pharmacist, pharmacist intern, or pharmacy technician; and
    - 3. A procedure for a patient record to be readily retrievable by manual or electronic means.
- (2) An applicant for a special pharmacy permit for clinical practice shall be exempt from the following:
  - (a) Prescription equipment requirements of 201 KAR 2:090, Section 2;
  - (b) Pharmacy sanitation requirements of 201 KAR 2:180; and
  - (c) Security and control of drugs and prescriptions requirements of 201 KAR 2:100, Sections 1, 2, 3, and 4.

Section 3. Pharmacy Closure. The permit holder shall provide notification to the board thirty (30) days prior to permanent pharmacy closure.

Section 4. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special pharmacy permit for clinical practice on either the Application for Special Pharmacy Permit for Clinical Practice or the Application for Special Pharmacy Permit for Clinical Practice Renewal; and
- (2) As appropriate, the:
  - (a) Initial application fee established by 201 KAR 2:050, Section 1(9); or
  - (b) Renewal application fee established by 201 KAR 2:050, Section 1(10).

Section 5. Incorporation by Reference.

- (1) The following material is incorporated by reference:
  - (a) "Application for Special Pharmacy Permit for Clinical Practice", Form 1, 5/2012; and
  - (b) "Application for Special Pharmacy Permit for Clinical Practice Renewal", Form 2, 5/2012.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m.

(39 Ky.R. 172; 458; eff. 9-19-2012.)

**201 KAR 2:350. Home medical equipment service providers.**

RELATES TO: KRS 315.512, 315.514, 315.518, 314.520

STATUTORY AUTHORITY: KRS 315.191, 315.518(1), (4), 315.520(4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191 authorizes the Board of Pharmacy to promulgate administrative regulations governing home medical equipment and service providers. This administrative regulation establishes the minimum requirements for the licensing of a home medical equipment service provider.

Section 1. General Requirements.

- (1) A home medical equipment company engaged in providing services in the Commonwealth shall apply for a license from the board in accordance with KRS 315.518 and this administrative regulation.
- (2) An agent or employee of a licensee shall not be required to obtain a license if the agent or employee is acting in the usual course of business or employment.
- (3) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:
  - (a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature, and humidity control, sanitation, space, and security;
  - (b) Establishing and providing records of annual continuing education for personnel engaged in the delivery, maintenance, repair, cleaning, inventory control, and financial management of home medical equipment and services; and
  - (c) Providing accurate and precise records of all goods shipped or received including source of receipt, date, quantity, itemized description, and any other information pertinent to the transaction.
- (4) An applicant for a home medical equipment license shall prepare and adopt a policy and procedure manual that sets forth a detailed description of how the:

- (a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and
- (b) Licensees will maintain the premises so that the home medical equipment remains secure.

## Section 2. Sanitation and Safety Requirements.

- (1) An applicant for a home medical equipment license located in the Commonwealth of Kentucky shall be inspected by the board prior to the issuance of the license.
- (2)(a) The designated business area shall be used exclusively for the sale, rental, and distribution of home medical equipment.
  - (b) Repairs and cleaning shall be done in a confined, properly ventilated area.
  - (c) All areas shall be adequately lighted and all areas kept in a clean and sanitary manner.
- (3) A home medical equipment supplier shall comply with the maintenance and cleaning requirements established in this subsection. A home medical equipment supplier shall:
  - (a) Maintain documents demonstrating that a function and safety check of equipment was performed prior to set up;
  - (b) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
  - (c) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
  - (d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
  - (e) Clean and disinfect equipment according to manufacturer's specifications;
  - (g) Perform routine inspection, service, and maintenance of equipment located in the patient's or customer's home according to manufacturers' specifications.
- (4) The supplier's services shall be available twenty-four (24) hours, seven (7) days per week if it is essential to the maintenance of life or lack of service might reasonably cause harm.
- (5) The supplier shall:
  - (a) Demonstrate that each piece of equipment has been checked, is free of defects, and operates within the manufacturer's specifications;
  - (b) Maintain documentation, which shall include the following:
    - 1. The type of equipment;
    - 2. The manufacturer;
    - 3. The model number;
    - 4. The serial number;
    - 5. The date of repair;
    - 6. The specific repair made; and
    - 7. The name of the person or company performing the repair;
  - (c) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
  - (d) Maintain all electrical components so that they do not present fire or shock hazard;
  - (e) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided;

- (f) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
  - (g) Affix an identifying label that contains the name of the provider, address, and phone number.
- (6) The supplier shall implement and maintain a written procedure at each location for handling complaints and problems. The procedure shall include a complaint file documenting complaints and problems and resolution of the complaints and problems.

#### Section 3. License Fee; Renewals.

(1) A home medical equipment and services provider shall be licensed by the board prior to engaging in providing home medical equipment and services in the Commonwealth.

(2) An applicant shall submit:

- (a) 1. A completed Application for Home Medical Equipment License; and
- 2. The initial application fee established by 201 KAR 2:050, Section 1(21); or
- (b) 1. A completed Application for Home Medical Equipment License Renewal; and
- 2. The renewal application fee established by 201 KAR 2:050, Section 1(22).

#### Section 4. Incorporation by Reference.

(1) The following material is incorporated by reference:

- (a) "Application for Home Medical Equipment License", Form 1, 10/2012; and
- (b) "Application for Home Medical Equipment License Renewal", Form 2, 10/2012.

(2) This form may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m.

(39 Ky.R. 655; 1375; eff. 2-1-2013.)

#### **201 KAR 2:360. Naloxone dispensing.**

RELATES TO: KRS 217.186

STATUTORY AUTHORITY: KRS 217.186, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 requires the Board of Pharmacy to promulgate administrative regulations governing dispensing of naloxone by a pharmacist pursuant to a physician-approved protocol. This administrative regulation establishes the minimum requirements for the pharmacist to be able to dispense naloxone pursuant to a physician-approval protocol.

Section 1. Certification. (1) A pharmacist desiring to achieve certification to initiate the dispensing of naloxone shall complete and submit an Application for Pharmacist Certification for Naloxone Dispensing, Form 1, with the board and provide the following:

- (a) Name;
- (b) Address;
- (c) Phone number;
- (d) Pharmacist license number; and

- (e) Proof of education and training in the use and dispensing of naloxone for treatment of opioid overdose pursuant to Section 5 of this administrative regulation.
- (2) The board shall issue the certification to a pharmacist who meets the requirements of subsection (1) of this section within thirty (30) days of the receipt of the application.

Section 2. Procedures for Dispensing of Naloxone. A pharmacist may initiate the dispensing of naloxone under the following conditions:

- (1) The pharmacist has met the requirements of Section 1 of this administrative regulation;
- (2) The pharmacist has received his or her certification;
- (3) The pharmacist has a physician-approved protocol that meets the minimum requirements of Section 3 of this administrative regulation; and
- (4) The pharmacist documents the dispensing event in the pharmacy management system including:
  - (a) Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
  - (b) Documentation that the individual receiving naloxone was provided with the required training and education pursuant to Section 4 of this administrative regulation.

Section 3. Protocol Minimum Requirements. A physician-approved protocol authorizing a pharmacist to initiate the dispensing of naloxone shall contain:

- (1) Criteria for identifying persons eligible to receive naloxone under the protocol;
- (2) Naloxone products authorized to be dispensed, including:
  - (a) Name of product;
  - (b) Dose; and
  - (c) Route of administration;
- (3) Specific education to be provided to the person whom the naloxone is dispensed;
- (4) Procedures for documentation of naloxone dispensation, including procedures for notification of the physician authorizing the protocol, if desired by the physician in accordance with KRS 217.186(5)(b)3;
- (5) The length of time the protocol is in effect;
- (6) The date and signature of the physician approving the protocol; and
- (7) The names and work addresses of pharmacists authorized to initiate dispensing of naloxone under the protocol.

Section 4. Education to be Provided to Person Receiving Naloxone Prescription Under Protocol. A pharmacist dispensing naloxone to a person shall provide verbal counseling and written educational materials, appropriate to the dosage form of naloxone dispensed, including:

- (1) Risk factors of opioid overdose;
- (2) Strategies to prevent opioid overdose;
- (3) Signs of opioid overdose;
- (4) Steps in responding to an overdose;
- (5) Information on naloxone;
- (6) Procedures for administering naloxone; and



- (7) Proper storage and expiration of naloxone product dispensed.

Section 5. Pharmacist Education and Training Required for Certification. A pharmacist who applies for certification to initiate dispensing of naloxone shall have received education and training related to the safe dispensing of opioids and use of naloxone as rescue therapy for opioid overdose, including:

- (1) Risk factors for opioid abuse and overdose;
- (2) Opioid overdose prevention;
- (3) Recognizing and responding to opioid overdoses;
- (4) Indications for use of naloxone as rescue therapy;
- (5) Contraindications for use of naloxone;
- (6) Administration of naloxone;
- (7) Adverse effects associated with naloxone rescue therapy;
- (8) Identification of a patient who meets the criteria for provision of naloxone;
- (9) Required education to provide to persons receiving naloxone;
- (10) Required elements of protocol to initiate dispensing of naloxone; and
- (11) Required documentation when initiating dispensing of naloxone.

Section 6. Incorporation by Reference.

- (1) "Application for Pharmacist Certification for Naloxone Dispensing", Form 1, 7/2015, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(41 Ky.R. 2691; Am. 42 Ky.R. 273 eff. 9-4-2015.)

**201 KAR 2:370. Pharmacy services in long-term care facility (LTCF).**

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: KRS 315.002, 315.005, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to ensure[insure] safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in long-term care facilities.

Section 1. Definition. **(1) "Immediate supervision" is defined by KRS 315.010(11).**

**(2)** "Long-term care facility" or "LTCF" means:

**(a)[(1)]** An intermediate care facility;

**(b)[(2)]** A skilled nursing facility;

**(c)[(3)]** A hospital other than an acute care hospital licensed pursuant to 902 KAR 20:016;

**(d)[(4)]** An intermediate care facility for intellectually and developmentally disabled; or

**(e)[(5)]** A personal care facility.

**(3) "Pharmacist-in-charge" means a pharmacist mandated as in charge under KRS 315.020 and who meets the requirements of 201 KAR 2:205.**

**(4) "Supervision" is defined by KRS 315.010(25).**

Section 2. General Requirements. (1) The pharmacist-in-charge of the dispensing pharmacy shall be responsible for policy and procedures governing the procurement, distribution, and control of all drugs that are provided to a long-term care facility.

(2) Dispensing.

(a) Medications shall be dispensed only on the medical order (for a non-controlled substance) or a prescription drug order of a licensed practitioner.

(b) A medical order (for a non-controlled substance) shall be considered a prescription drug order if it is entered on the medical record of a patient at an LTCF and if the medical order contains the:

1. Name of patient;
2. Date of issuance;
3. Name, strength, and dosage form of drug prescribed;
4. Directions for use;
5. Quantity of length of therapy as defined in policy and procedures or as defined by medical order; and
6. Practitioner's name.

(3) Emergency Drugs.

(a) The pharmacist-in-charge of the dispensing pharmacy shall establish policy and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include **controlled substances stocked pursuant to 902 KAR 55:070 that shall not exceed six (6) individual doses of six (6) different controlled substances, [only thirty six (36) items, six (6) deep of which controlled substances are stocked pursuant to 902 KAR 55:070]** and whose prompt use and immediate availability are generally regarded ~~[by the pharmacy and therapeutics committee]~~ as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be included in the emergency kit based upon evidence of use.

(d) Emergency drug stock shall be inspected by pharmacy personnel on at least a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(e) Emergency drug stock shall not be stocked in a personal care facility.

(4) Long Term Care Facility Pharmacy Stock.

(a) Pharmacy stock of drugs **in an LTCF** shall **not exceed fifteen (15) individual doses each off [be limited in number to]** 150 non-controlled substances ~~[substance items fifteen (15) deep]~~.

(b) Pharmacy stock of drugs in a personal care facility shall **not exceed five (5) individual doses each off [be limited in number to]** thirty (30) non-controlled substances ~~[, five (5) deep]~~.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be placed in pharmacy stock based upon evidence of use.

(d) The pharmacist-in-charge shall be responsible for authenticating the need for pharmacy stock.

(e) A pharmacist shall review the prescription drug or medical order before the release of medication.

- (f) Pharmacy stock shall be inspected by pharmacy personnel on at least a monthly basis and documentation maintained to determine if contents have become outdated and if stocks are being maintained at adequate levels.
- (g) Pharmacy stock shall be used for a patient for no more than the next business day.
- (h) Except for pharmacy stock of intravenous fluids with no additive drugs or irrigation solutions, the pharmacy stock shall be replenished by:
  - 1. A secure box delivered by the pharmacy; or
  - 2. A pharmacist or a pharmacist intern, or a certified pharmacy technician, who shall be under the immediate supervision of a pharmacist on-site, unless there is a pharmacy on-site, then the pharmacy stock shall be replenished by a pharmacist or a pharmacist intern or a certified pharmacy technician under the ~~general~~ supervision of a pharmacist on-site.

JOEL THORNBURY, President

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### **GENERIC LABELING STATEMENT**

The Kentucky Board of Pharmacy has addressed generic labeling and has come up with these alternatives when product selection is utilized. Alternatives the Board recognizes in lieu of using just the name of the drug dispensed on the label of the prescription container when product selection [substitution] is made are as follows:

- 1) Methyldopa “generic substitution made for” Aldomet;
- 2) Methyldopa “dispensed in place of” Aldomet;
- 3) Methyldopa “substituted for” Aldomet;
- 4) Methyldopa “dispensed for” Aldomet;
- 5) Methyldopa “generic as” Aldomet.

The label must refrain from wording such as ‘same as’ or any inference that the substitution is the same as the trade name drug. Using only the trade name and the generic name on the label is not acceptable when denoting drug product selection. These alternatives were adopted by the Board to meet the requirement when the physician requests that both names appear on the label. This also should help those pharmacists supplying nursing homes and are required to have the name of the medication as it appears on the physician’s order in the chart.